Decree Concerning Medical Devices
No. 16/ 2006. (III. 27.)EüM of the Minister of Health

Authorised by Article 247, paragraph (2) f) and k) of Act CLIV of 1997 on Health Care to
perform the obligations set out in Article 101 of the Act, the following is ordained:
Scope

Article 1

(1) This Decree shall apply to medical devices and their accessories manufactured,
marketed, and applied in the Republic of Hungary, except for those listed in paragraph (2) .
(2) This Decree shall not apply to:
a) in vitro diagnostic devices;
b) human blood, blood products, plasma or blood cells of human origin or to devices which
incorporate at the time of placing on the market such blood products, plasma or blood cells,
with the exception of devices referred to in Article 2(2d);
c) products incorporating tissues or cells of human origin or to transplants or tissues or
cells of human origin;
d) devices incorporating tissues or cells of animal origin except for items specified in
Article 2(2a) or to transplants or tissues or cells of animal origin;
e) products designated by a proprietary status as medicaments concerning also medicinal
products made of human blood derivatives except for those listed in Article 2(2b) (2d);
f) devices originally intended for use as personal protective equipment that are covered by
Act XCIII of 1993
g) cosmetic products covered by special rule.

Declaratory directions
Article 2

(1) For the purposes of this Decree,
a) medical device means any instrument, apparatus, appliance, material or other article,

whether used alone or in combination, including the software necessary for its proper
application, as well as custom-made devices and devices for clinical investigation intended by
the manufacturer to be used for human beings for the purpose of:
aa) diagnosis, prevention, monitoring, treatment or alleviation of disease,
ab) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or
handicap,
ac) investigation, replacement or modification of anatomical structure or of a physiological
process,
ad) control of conception
and which does not achieve its principal intended action in or on the human body by
pharmacological, immunological or metabolic means, but which may be assisted in its
function by such means; b) accessory means any product not covered by a), which whilst not being a medical
device is designed specifically to be used together with the medical device to facilitate its
original use in accordance with the purpose intended expressly by the manufacturer;
(items defined in a) and b) will be hereinafter referred to aggregately as devices);
c) custom-made device means any device specifically made in the course of therapy of a
particular patient upon request from a professional on the basis of special rule to prescribe
as demanded by the therapeutic requirements such items with specific design characteristics
and intended for the sole use of the patient. Mass-produced devices (i.e. dental filling
materials, orthotic devices) which are adapted to meet individual requirements are not
considered to be custom-made devices.
d) device intended for clinical investigation means any device intended for use by a duly
qualified medical practitioner when conducting investigations for the purposes determined in
Section 2.1 of points A and B of Annex 10 on clinical evaluation;
e) manufacturer means the natural or legal person or economic organisation without legal
personality
ea) with responsibility for the design, manufacturing, packaging and labelling

of a device
before it is placed on the market under his own name, regardless of whether these operations
are carried out by himself or on his behalf by a third party;
eb) who assembles, packages, processes, fully refurbishes and/or labels devices and assigns
to them their intended purpose as a device with a view to their being placed on the market
under his own name. This clause shall not apply to the person who assembles or adapts
devices already on the market to their intended purpose as required to meet the individual
needs arising in the course of therapy of an individual patient;
f) intended purpose means the use for which the device is intended according to the data
supplied by the manufacturer on the labelling, in the instructions for use and/or in promotional
materials;
g) placing on the market means the first making available in return for payment or free of
charge of a device other than those intended for clinical investigation, with a view to
distribution and/or use in a Member State of the European Economic Area (hereinafter
referred to as EEA) or in a state of the same rights on the basis of treaty (hereinafter referred
to as EEA Member State), regardless of whether the device is new or fully refurbished; h)
putting into service means the stage when the device has been made available to the final user
in the EEA Member State for the first time for its intended purpose;
i) notified body means a body designated as ordained by special rule for carrying out
the tasks concerning the assessment, supervision, and certification of devices, and notified to
the European Commission (hereinafter referred to as Commission) as well as to the EEA
Member States, furthermore the notification has been accomplished at the Commission
therefore it has an identification number given by the Commission. Provisions relating to the
notified body of this decree shall apply only to bodies notified on the basis of the special rule ;
j) adopted and harmonised standard means European standards approved by the

European
Standards Organisations and published in the Official Journal of the European Community;
furthermore, which have been published as national standard according to the Hungarian
prevailing practice;
k) active medical device means any medical device relying for its functioning on any source
of power other than that directly generated by the human body or gravity;
l) active implant means any active medical device which is intended to be totally or
partially introduced surgically or by other medical intervention into the human body or into a
natural orifice, and which is intended to remain after the procedure;
m) authorised representative means any natural or legal person or economic organisation
without legal personality who has residence or registered place of business in an EEA Member
2 State and who, explicitly designated by the manufacturer, acts and may be addressed by
authorities and bodies instead of the manufacturer with regard to the latter’ s obligations under
this Decree.
n) hip, knee or shoulder replacement means an implantable component part of a total joint
replacement system which is intended to provide a function similar to that of either a natural
hip joint, a natural knee joint or a natural shoulder joint. Ancillary components (screws,
wedges, plates and instruments) are excluded from this definition.
(2) The term medical device also comprises a) the device manufactured utilising nonviable animal tissue or cell;
b) the device intended to administer medicinal products but is not considered as single-use
combined drug and applicator unit, which is to be placed on the market as medicinal product;
c) the device incorporating, as an integral part, a substance which, if used separately
considered to be a medicinal product and which is liable to act upon the body with action
ancillary to that of the device;
d) the device incorporating, as an integral part, a substance which, if used separately, may
be considered to be a medicinal product constituent or a medicinal product derived from

human blood or plasma which is liable to act upon the human body with action ancillary to
that of the device (hereinafter referred to as a “human blood derivative”).
(3) Where a device according to paragraph (2) a), is manufactured utilising tissues of
bovine, ovine and caprine species, as well as deer, elk, mink and cats origin, also
requirements ordained by special rule shall be applied.
(4) In case of doubt in the question if the product shall be considered as medical device the
Office of Health Authorisation and Administrative Procedures (hereinafter referred to as
Authority) shall decide in resolution.
Essential regulations

Article 3

(1) Medical devices with the exception of devices defined in Article 2(1c) and (1d)
may be placed on the market if bearing the CE marking set out in paragraph (2).
(2) Medical devices may bear the CE marking if
a) they fulfil the essential requirements contained by Article 4, and
b) to certify the requirements contained in a) the devices have been subject to the
assessment of their conformity in accordance with the provisions of Article 6.

Requirements concerning medical devices, assessment of conformity
Article 4

(1) All devices placed on the market or put into service must comply with the relevant
essential requirements set out in Annex 1.
(2) In cases when the device conforms to the relevant adopted and harmonised standard,
the fulfilment of details of essential requirements which apply to them specified by the
relevant standard must be presumed. The Hungarian Standards Institution publishes the list of
the adopted and harmonised standards in its official journal.
(3) As appropriate, paragraph (2) shall apply to the relevant provisions of European
Pharmacopoeia in case of interaction of devices and medicinal products

furthermore specially
in case of surgical sutures and dressings.
3 (4) In the case of devices defined in Article 2(2b), the essential requirements specified in
Annex 1 shall be applied only to the assessment of properties influencing the safety and the
performance of the device.

Classification

Article 5
(1) In order to select the appropriate conformity assessment procedure, manufacturers shall
devide their devices into Classes I, IIa, IIb, and III in accordance with Annex 9.
(2) In case of active implants and their accessories the classification procedure should not be
performed. For active implants conformity assessment procedure set out in Article 6 (6) shall be
followed.
(3) In case of doubt in the question arising for the application of the classification rules,
the Authority shall decide in resolution.
(4) Breast implants shall be classified as medical devices falling within Class III.; in this
case rules of Annex 9 are not applicable.
(5) Hip, knee or shoulder replacements shall be classified as medical devices falling within
Class III.; in this case rules of Annex 9 are not applicable.

Conformity assessment procedures

Article 6
(1) In the case of devices falling within Class III, the manufacturer may choose:
a) the procedure of conformity set out in Annex 2 (full quality-assurance), or

b) the procedure relating to the type-examination set out in Annex 3, coupled with
ba) the product assessment procedure set out in Annex 4, or
bb) the production quality-assurance procedure set out in Annex 5.
(2) In the case of devices falling within Class IIa, the manufacturer declining the procedure
referred to paragraph (3) a) shall follow the procedure relating to the declaration of

conformity set out in Annex 7, coupled with either:
a) the product verification procedure set out in Annex 4, or
b) the production quality assurance procedure set out in Annex 5, or
c) the product quality assurance procedure set out in Annex 6.
(3) In the case of devices falling within Class IIb, the manufacturer may choose:
a) the procedure set out in Annex 2 (full quality assurance); in this case, Section 4 of Annex
2 is not applicable; or
b) the type-examination procedure set out in Annex 3, coupled with
ba) the product verification procedure set out in Annex 4, or
bb) the production quality assurance procedure set out in Annex 5, or
bc) the product quality assurance procedure set out in Annex 6.
(4) In the case of devices falling within Class I, the manufacturer shall follow the
procedure referred to in Annex 7 and draw up a declaration of conformity required before
placing the device on the market.
(5) The conformity assessment procedures set out in paragraph (1) through (4) cannot be
applied to custom-made devices, to devices intended for clinical investigation, or in cases
defined in Article 8. In case of custom-made devices procedure set out in paragraph (7) shall
4 be followed. In case of devices intended for clinical investigation the manufacturer is required
to draw up the declaration of conformity according to Annex 8.
(6) In the case of active implantable medical devices other than devices which are
custom-made or intended for clinical investigations the manufacturer may choose:
a) the procedure set out in Annex 2 (full quality assurance), or
b) the type-examination procedure set out in Annex 3, coupled with
ba) the product verification procedure set out in Annex 4, or
bb) the production quality assurance procedure set out in Annex 5.
(7) In the case of custom-made devices, the manufacturer shall follow the procedure
referred to in Annex 8, as well as draw up the statement set out in Section 2.1(e) of points A and
B of Annex 8 and compile the documentation referred to in Section 3.1 of points A and B of
Annex 8 before placing the device on the market. The documentation shall be kept for a period
of 5 years and submitted to the Authority on request.

(8) During the conformity assessment procedure for a device, the manufacturer and/or the
notified body shall take account of the result of any assessment and verification operations,
which have been carried out in accordance with this Decree at an intermediate stage of
manufacture.
(9) The procedures provided for in Annexes 3, 4, 7 and 8 may be initiated by the authorised
representative when charged by the manufacturer.

Article 7
(1) The notified body may require, where duly justified, any information or data which is
necessary for establishing, monitoring, and certifying conformity, as well as maintaining the
attestation of conformity in view of the chosen procedure. The documents relating to the
procedures referred to in Article 6 (1) to (7) shall be in Hungarian or in an official language of
another EEA Member State acceptable to the notified body.
(2) Certificates of conformity issued by the notified bodies in accordance with Annexes 2
and 3 shall be valid at most for five 5 years. The certificate may be extended once only, on
application made at a time specified in an agreement between the parties or at request
submitted 3 months before expiry when no such agreement exists for a further period of 5
years at maximum.
(3) The manufacturer or the authorised representative and the notified body shall draw up
a contract on the conditions of performing the assessments and tests set out in Annexes 2
through 6.
(4) In order to fulfil public health interests or therapeutic purpose for medically justified
request, by the previous endorsement of the competent professional college, at most for 1
year, for a determined health care provider, the Authority is authorised to make exceptions
and grant licences for putting into service and for the usage of a specific device that have not
been submitted to the procedures included in Article 6 (1) to (7), if substitution of the specific

device for other one already on the market is not possible.
(5) When the conformity assessment procedure involves the intervention of a notified
body and there are several bodies assigned to perform the procedure, the manufacturer or
the authorised representative are entitled to choose the notified body conducting the
assessment procedure.
(6) When the notified body ascertains that the manufacturer does not comply with this
decree or the conformity assessment document should not have been issued, the notified body
considering all the circumstances suspends or withdraws its conformity assessment
document unless, on request of the notified body, the manufacturer, by taking the appropriate
5 measures within the deadline appointed, ensures conformity with this Decree or conditions
required to deliver the certificate.
(7) The notified body is obliged to inform the Authority on all activities related to
conformity assessment set out in this decree including certifying activity, changes,
amendments, suspensions, withdrawals and refusals based on this decree - using the printed or
electronic version of the form supplied by the Authority and the other notified bodies. On the
basis of the information supplied by the notified body the Authority shall notify the
Commission and the EEA Member States. Furthermore the notified body supplies with all the
relevant information on request of the Authority.
(8) The Authority shall perform professional inspection of the notified body on request of
the Designation Committee according to special rule or on initiative of the notified body
itself. The Authority shall give account of the result of the professional inspection to the
Designation Committee.

Article 8
(1) By way of derogation from Article 6, paragraphs (2) through (6) of this Article shall
apply to multicomponent systems and procedure packs.

(2) Any natural or legal person or economic body without a legal personality who puts
devices bearing the CE marking together within their intended purposes and within the
limits of use specified by their manufacturers in order to place them on the market as a kit
or device system, shall draw up a declaration by which he states that:
a) he has verified the mutual compatibility of the devices in accordance with the
manufacturers' instructions and has carried out his operations in accordance with these
instructions;
b) the packing of the system or procedure pack packed by the manufacturer itself and the
enclosed directions for use are consistent with the instructions supplied by manufacturer(s);
c) the whole activity has been subjected to internal supervision and inspection.
(3)Any natural or legal person or economic organisation without legal personality who
sterilise for the purpose of placing on the market, systems or procedure packs referred to in
paragraph (2) or other CE-marked medical devices designed by their manufacturers to be
sterilised before use, shall at his choice follow one of the procedures referred to in Annexes 4,
5 or 6. The application of the regulations set out in these Annexes and the interventions of the
notified body are limited to procedures intended to obtain sterility. Concomitantly, the person
responsible for sterilisation shall draw up a declaration stating that sterilisation has been
carried out in accordance with the manufacturer's instructions.
(4) The products referred to in paragraphs (2) and (3) themselves shall not bear an additional
CE marking, but shall be accompanied by the information referred to in Section 13 of point A
of Annex 1, which includes the instructions supplied by the manufacturers of the devices which
have been put together.
(5) The declarations referred to in paragraphs (2) and (3) shall be preserved for a period of
5 years and submitted to the Authority upon request.
(6) In cases where the kit or system incorporates devices which do not bear a CE marking

or where the chosen combination of devices is not compatible in view of their original
intended use, the kit or system shall be treated as a device in its own right and as such be
subjected to the relevant assessment and certification procedure set out in Article 6.

Devices intended for clinical investigations

6 Article 9

(1) The professional-ethical opinion according to paragraph (1) of Article 10 of the decree
No. 23/2002. (V. 9.) EüM on medical scientific researches performed on human being
(hereinafter referred to as decree on medical scientific researches) or the professional-ethical
authorization according to Article 20/D of the same decree shall be notified to the Authority
by the body competent to issue them, within 5 days, by means of sending the copy of the
opinion or the authorization. The manufacturer or his authorized representative shall act
according to Annex 8. Otherwise rules of decree on medical scientific researches applies to
clinical investigations.
(2) Clinical investigations must be conducted in accordance with the provisions of Annex
10. The manufacturer shall submit the report referred to in Section 2.3.7 of points A and B of
Annex 10 to the Authority upon request.
(3) The provisions of paragraphs (1) and (2) shall apply also in cases where the clinical
investigations are conducted using devices bearing the CE marking but the aim of these
investigations is to use the devices for a purpose other than that referred to in the relevant
conformity assessment procedure. Nevertheless, the relevant provisions of Annex 10 remain
applicable.
(4) The Authority shall make out a certificate on the notification referred to in paragraph
(1) which is condition of starting of the clinical investigation.

Registration
Article 10
(1) Any manufacturer having registered place of business in the Republic of Hungary, who
manufactures devices under his own name in accordance with the procedures referred to in
Article 6 (4) and (7) and any other natural or legal person engaged in the activities referred to
in Article 8 (2) and (3) shall inform the Authority of his name, the address of the seat and the
registered place of business, the description of the devices concerned, furthermore the
changes of these data by means of the Form or its electronic counterpart available from the
Authority.
(2) Where a manufacturer does not have a registered place of business in the EEA, he shall
designate an authorised representative in one of the Member States. If the registered place of
business of the authorised representative is in the Republic of Hungary the authorised
representative shall inform the Authority of his name, registered place of business and
description of the devices concerned, as well as any change in the data by means of the Form
or its electronic counterpart available from the Authority.
(3) The Authority acknowledges the fact of registration according to paragraphs (1) and (2)
in written form. The Authority shall forward data of the registration to the European databank.
(4) The designation, address, and place of business of the manufacturer and the authorised
representative shall be displayed on the packaging of individual devices and product batches,
as well as in the instructions for use of the device.
(5) For all medical devices of class IIb and III, the Authority may request to be informed of
all data allowing for identification of such devices together with the label and the instructions
for use when such devices are put into service in the Republic of Hungary.

Registration fee

Article 11

The applicant who initiates the registration procedure referred to in Article 10 shall pay a
fee (per device group) set out in special rule for the administrative procedure services
delivered.

Provisions in connection with data managing
Article 12
(1) In case of implantation of an implant for the sake of further treatment and healthcare
provision of the patient the healthcare provider shall keep a special record which contains
the patient’ s name, the date of birth, availability of the patient, the date of implantation, the
name of the implantatum indicating together with the name of the manufacturer, the type
and the serial number.
(2) When applying this Decree provisions involved in special rules relating on the
confidential handling of data shall be observed.

Marking of conformity
Article 13
(1) The CE marking of conformity, must appear as shown in Annex 11, in a visible, legible
and indelible form on the device, its sales packaging and on the instructions for use.
(2) In the case of devices placed on the market in sterile condition, the CE marking must
appear on both the sterile and the sales packaging.
(3) It is prohibited to affix marks or inscriptions which are likely to mislead third parties with
regard to the meaning of the graphics of the CE marking, or reduce the visibility and legibility
of the CE marking. Any other mark may be affixed to the device, to the packaging or to the
instruction leaflet accompanying the device provided that the visibility and legibility of the
CE marking is not thereby reduced.
(4) Following any modification of the device that influences its safe application, the CE
marking may be affixed only after the completion of reassessment by the relevant procedures

set out in Article 6.
(5) When any of the procedures set out in Annexes 2, 4, 5, or 6 have been applied during
conformity assessment, the identification number of the involved notified body shall be
affixed to the device along with the CE marking.
(6) At trade fairs, exhibitions, demonstrations showing the devices which don’ t conform to
this Decree may only be on display provided that a visible sign clearly indicates that the
device don’ t conform to this Decree and/or the prescribed conformity assessment procedure
has not been carried out.
(7) Where the devices are subject to other decrees concerning other aspects and which also
provide for the affixing of the CE marking, the latter shall indicate that the devices also fulfil
the provisions of the other decrees unless provided differently by applicable law.

Reporting on incidents and unexpected events following placing of devices on the
market
Article 14
8 (1) The manufacturer, the distributor, the authorised representative, as well as the medical
practitioner or the medical institution shall inform the Authority within 3 days according to
Annex 12 on all data of any adverse event occurred in connection with devices. Reporting is
obligatory whenever any malfunction or deterioration of in the characteristics and/or
performance of a device, as well as any inadequacy in the labelling or the instructions for use
might lead to or might have led to the death of a patient or user or to a serious deterioration in
his state of health.
(2) The manufacturer, the distributor, or the authorised representative shall report to the
Authority according to the paragraph (1), if the manufacturer or the authorised representative
has recalled devices systematically due to any cause referred to in the aforementioned paragraph
or due to any technical cause or therapeutical one.
(3) Unless the notification was made by the manufacturer or the authorised

representative,
the Authority shall immediately within 8 days at the latest upon its acknowledgement
inform the manufacturer or his authorised representative.

Article 15
(1) Where the Authority ascertains that the devices bearing the CE marking, when correctly
installed, maintained and used for their intended purpose, may compromise the health and/or
safety of patients, users, or other persons, the Authority shall adopt a resolution:
a) on suspension of the use or placing of such device on the market, or
b) on recall of the device from the market, or on prohibition of use of the device,
furthermore the Authority shall inform the Commission and the EEA Member States ,
especially on non-conformity with essential safety and health protection requirements
determined in Annex 1 and on incorrect application of the adopted harmonised standards or
their insufficiencies, by indicating the causes.
(2) When it is ascertained that the assessment of conformity has not been performed or
was conducted improperly, the Authority shall take the measures referred to in paragraph (1)
a) or b).
(3) If the device involved in a case defined in paragraph (1) the Authority shall notify the
General Inspectorate for Consumer Protection (Fogyasztóvédelmi Ffelügyelség) to take
measures prescribed by applicable law.
(4) Concomitantly with the measures referred to in paragraphs (1) through (3), the
Authority shall inform the manufacturer or the authorised representative without delay.
(5) On the basis of the decisions referred to in paragraphs (1) and (3), and the measures by
the General Inspectorate for Consumer Protection the list of devices recalled, the names of
their manufacturers and the authorised representatives shall be published in the official
journal of the Ministry of Health.

Placing of devices without a CE marking on the market, illicit use of the CE marking

Article 16
(1) When CE marking has not been affixed on the device or it has been affixed unduly,
the Authority shall ordain the withdrawal or the suspension of placing of the device on the
market, whether or not safety is endangered, unless on request of the Authority, the
manufacturer or his authorised representative, by taking the appropriate measures within the
deadline appointed, ensures conformity with this Decree or conditions required to affixing the
CE marking. Prosecutory action shall be conducted as set out in Article 15.
9 (2) Paragraph (1) shall apply also in cases where CE marking has been affixed according
to this Decree, but it has been affixed on products falling out of the scope of this Decree.

Periodical inspection
Article 17
(1) Users of devices described in Annex 13 are obliged to arrange for periodic inspection
of devices in order to identify any malfunctioning that results from ordinary depreciation,
the deterioration of parameters specified in the technical documentation, and to ascertain the
application for the intended purpose and the safety of performances.
(2) The frequency of periodic inspections and other pertinent regulations are described in
Annex 13.
(3) The periodic inspections shall be conducted by notified bodies or other organisations
having the decision of the Authority on entitling to perform periodical inspection.

Supervision
Article 18
(1) The compliance of users with the requirements of the safe operation of devices for the
intended purposes shall be supervised regularly by the competent regional institute of the
National Public Health and Medical Officer’ s Service (llami
N é peg é szs é g ü gyi é s

Tisztiorvosi Szolgálat, hereinafter: the Institute) authorised to license health care providers.
This shall be accomplished using the documents and records available as the result of the licensing procedure and the supervisions.
(2) When it is concluded that the user does not fulfil the obligations ordained by this Decree, especially by Article 17, the Institute shall require the user to restore the documentation and the performance of the device to the level specified in the technical documentation and shall set a term for the completion of the relevant operations. When the user fails to meet the request, the Institute shall suspend the application of the device in question temporarily or if necessary, initiates with the Authority the withdrawal of the device from use.
(3) When according to the results of the periodic inspection it is reasonably presumed that the device does not meet the requirements set out in Article 4 or the conformity assessment procedure referred to in Article 6 has not been performed or has been conducted improperly, the Institute shall suspend the use of the device and concomitantly notify the Authority and the National Health InsuranceFund.
(4) Users concerned by decisions made according to paragraphs (2) and (3) by the Institute are entitled to submit an appeal according to special rule.
(5) The manufacturer, the distributor or the authorised representative is obliged to inform the National Institute of Chemical Safety of Fodor József National Centre for Public Health (hereinafter referred to as OKK-OKBI) on medical devices containing active substance that is considered as biocidal one according to dictinct rule intended expressly for disinfection of medical devices of class IIa, placed on the market in the previous calendar year, by means of the registration form according to Annex 14, until 1 March in every year. The OKK-OKBI shall forward the list prepared according to the notifications to the National Chief Medical

Officer's Office.

10 Implementation, transitional provisions

Article 19
(1) This Decree, except provisions set out in paragraph (2), shall come into effect on the 15
th
day following the day of publishing.
(2) Article 4(3) of this Decree takes effect as per the relevant special legal regulation.
(3) By coming into effect of this Decree concomitantly the following provisions become
invalid
a) the Decree No. 47/1999. (X. 6.) EüM on medical devices, furthermore on the

amendment of this Decree the Decree No. 29/2002. (V. 24.) EüM, the Decree No. 27/2003.
(V. 16.) ESZCSM, as well as the Decree No. 4/2005. (II. 25.) EüM,
b) the detail "Article 22 of Decree No. 47/1999. (X. 6.) EüM on medical devices and
Article 12(3) of the amending Decree No. 29/2002. (V. 24.) EüM." in the wording of Article
17(b) of Decree No. 8/2003. (III. 13.) ESZCSM on in-vitro diagnostic medical devices,
c) the Article 1 of Decree No. 12/2003. (III. 28.) ESZCSM on amendment of minister's
decrees in connection with foundation of the Office for Authorisation and Administrative
procedures of the Ministry of Health, Social and Family Affaires,
d) the Article 1 and 2 as well as paragraph (2) and (3) of Article 5 of the Decree No.
51/2004. (V. 21.) ESZCSM on amendment of health minister's decrees for the purpose of
legal harmonization.
(4) By coming into effect of this Decree concomitantly the Decree No. 48/1999. (X. 6.)
EüM concerning the designation of notified bodies commissioned
for the assessment, monitoring, and certification of medical devices operated under the technical supervision of the Minister of Health shall be completed with the Article
21 as follows:
"Article 21
This Decree contains regulations compatible with
a) the Council Directive 90/385/EEC (20 June 1990) on the approximation of the

laws of
the Member States relating to active implantable medical devices, Article 11 (2) and
(3), Annex VIII;
b) The Council Directive 93/42/EEC (14 June 1993) concerning medical devices, Article
16 (2) and (3), Annex XI"
(5) This Decree contains regulations compatible with
a) the Council Directive 90/385/EEC (20 June 1990) on the approximation of the laws of
the Member States relating to active implantable medical devices, Article 11 (2) and (3),
Annex VIII;
b) the Council Directive 93/68/EEC of 22 July 1993 amending Directives 87/404/EEC
(simple pressure vessels), 88/378/EEC (safety of toys), 89/106/EEC (construction products),
89/336/EEC (electromagnetic compatibility), 89/392/EEC (machinery), 89/686/EEC

(personal protective equipment), 90/384/EEC (non-automatic weighing instruments),
90/385/EEC (active implantable medicinal devices), 90/396/EEC (appliances burning gaseous
fuels), 91/263/EEC (telecommunications terminal equipment), 92/42/EEC (new hot-water
boilers fired with liquid or gaseous fuels) and 73/23/EEC (electrical equipment designed for
use within certain voltage limits), Article 9;
c) the Council Directive 93/42/EEC (14 June 1993) concerning medical devices, except
Article 1 (2c), Article 16 (2) and (3), Article 21 (1) and (2), and Annex XI.
d) the Directive 98/79/EC of the European Parliament and of the Council (27 October
1998) on in vitro diagnostic medical devices, Article 21 (2);
11 e) the Directive 2000/70/EC of the European Parliament and of the Council (16 November
2000) amending Council Directive 93/42/EEC as regards medical devices incorporating stable
derivates of human blood or human plasma;
f) the Directive 2001/104/EC of the European Parliament and of the Council of 7
December 2001 amending Council Directive 93/42/EEC concerning medical devices.

g) the Commission Directive 2005/50/EC (11 August 2005) on the reclassification of hip,

knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC
concerning medical devices.
ANNEX 1
to Decree of the Minister of Health No. 16/2006. (III. 27.)EüM

Essential requirements
A. In case of classified devices:
I. General requirements
1. The devices must be designed and manufactured in such a way that, when used under
the conditions and for the purposes intended, they will not compromise the clinical condition
or the safety of patients, or the safety and health of users or, where applicable, other persons,
provided that any risks which may be associated with their use constitute acceptable risks
when weighed against the benefits to the patient and are compatible with a high level of
protection of health and safety.
2. The solutions adopted by the manufacturer for the design and construction of the devices
must conform to safety principles, taking account of the generally acknowledged state of the
art. In selecting the most appropriate solutions, the manufacturer must apply the following
principles in the following order:
a) eliminate or reduce risks (inherently safe design and construction),
b) where appropriate take adequate protection measures including alarms if necessary, in
relation to risks that cannot be eliminated.
c) inform users of the residual risks due to any shortcomings of the protection measures
adopted.
3. The devices must achieve the performances intended by the manufacturer and be
designed, manufactured and packaged in such a way that they are suitable for one or more of
the functions referred to in Article 2 (a), as specified by the manufacturer.
4. The characteristics and performances referred to in Sections 1, 2 and 3 must not be
adversely affected to such a degree that the clinical conditions and safety of the patients and,
where applicable of other persons are compromised during the lifetime of the device as

indicated by the manufacturer, when the device is subjected to the stresses which can occur
during normal conditions of use.
5. The devices must be designed, manufactured and packed in such a way that their
characteristics and performances during their intended use will not be adversely affected
during transport and storage taking account of the instructions and information provided by
the manufacturer.
6. Any undesirable side-effect must constitute an acceptable risk when weighed against the
performances intended.

II. Requirements regarding design and construction
12 7. Chemical, physical and biological properties
7.1. The devices must be designed and manufactured in such a way as to guarantee the
characteristics and performances referred to in Section I on the General requirements.
Particular attention must be paid to:
a) the choice of materials used, particularly as regards toxicity and. where appropriate
flammability,
b) the compatibility between the materials used and biological tissues, cells and body
fluids, taking account of the intended purpose of the device.
7.2. The devices must be designed, manufactured and packed in such a way as to minimize
the risk posed by contaminants and residues to the persons involved in the transport, storage
and use of the devices and to the patients, taking account of the intended purpose of the
product. Particular attention must be paid to the human tissues exposed and to the duration
and frequency of exposure.
7.3. The devices must be designed and manufactured in such a way that they can be used
safely with the materials, substances and gases with which they enter into contact during their
normal use or during routine procedures; if the devices are intended to administer medicinal
products they must be designed and manufactured in such a way as to be compatible with the

medicinal products concerned according to the provisions and restrictions governing these
products and that their performance is maintained in accordance with the intended use.
7.4. Where a device incorporates as an integral part, a substance which, if used separately,
is considered to be a medicinal product and which is liable to act upon the body with action
ancillary to that of the device, the safety, quality and usefulness of the substance must be
verified according to the methods prescribed in Annex 1 of the decree 52/2005. (XI. 18.)EüM
on placing on the market of medicinal products for human use, taking account of the intended
purpose of the device.
Where a device incorporates, as an integral part, a human blood derivative, the notified
body shall seek a scientific opinion from the European Agency for the Evaluation of
Medicinal Products (EMEA) on the quality and safety of the derivative. Usefulness of the
derivative, as an integral part of the device, must be examined taking account of the intended
purpose of the device.
In the case of human blood derivatives a sample from each batch of bulk and/or finished
product shall be tested by a laboratory designated for that purpose in accordance with the
appropriate methods specified by the legal regulation on the registration of medicines.
7.5. The devices must be designed and manufactured in such a way as to reduce to a
minimum the risks posed by substances leaking from the device.
7.6. Devices must be designed and manufactured in such a way as to reduce, as much as
possible, risks posed by the unintentional ingress of substances into the device taking into
account the device and the nature of the environment in which it is intended to be used.
8. Infection and microbial contamination
8.1. The devices and manufacturing processes must be designed in such a way as to
eliminate or reduce as far as possible the risk of infection to the patient, user and third parties.
The design must allow easy handling and, where necessary, minimize

contamination of the
device by the patient or vice versa during use.
8.2. Tissues of animal origin must originate from animals that have been subjected to
veterinary controls and surveillance adapted to the intended use of the tissues. Notified bodies
shall retain information on the geographical origin of the animals. Processing, preservation,
testing and handling of tissues, cells and substances of animal origin must be carried out so as
13 to provide optimal security. In particular safety with regard to viruses and other transferable
agents must be addressed by implementation of validated methods of elimination or viral
inactivation in the course of the manufacturing process.
8.3. Devices delivered in a sterile state must be designed, manufactured and packed in a
non-reusable pack and/or according to appropriate procedures to ensure that they are sterile
when placed on the market and remain sterile, under the storage and transport conditions laid
down, until the protective packaging is damaged or opened.
8.4. Devices delivered in a sterile state must have been manufactured and sterilized by an
appropriate, validated method.
8.5. Devices intended to be sterilized must be manufactured in appropriately controlled
environmental etc. conditions.
8.6. Packaging systems for non-sterile devices must keep the product without deterioration
at the level of cleanliness stipulated and, if the devices are to be sterilized prior to use,
minimize the risk of microbial contamination; the packaging system must be suitable taking
account of the method of sterilization indicated by the manufacturer.
8.7. The packaging and/or label of the device must distinguish between identical or similar
products sold in both sterile and non-sterile condition.
9. Construction and environmental properties
9.1. If the device is intended for use in combination with other devices or equipment, the
whole combination, including the connection system must be safe and must not impair the
specified performances of the devices. Any restrictions on use must be

indicated on the label
or in the instructions for use.
9.2. Devices must be designed and manufactured in such a way as to remove or minimize
as far as is possible:
a) the risk of injury, in connection with their physical features, including the
volume/pressure ratio, dimensional and where appropriate ergonomic features.
b) risks connected with reasonably foreseeable environmental conditions, such as magnetic
fields, external electrical influences, electrostatic discharge, pressure, temperature or
variations in pressure and acceleration.
c) the risks of reciprocal interference with other devices normally used in the investigations
or for the treatment given.
d) risks arising where maintenance or calibration are not possible (as with implants), from
ageing of materials used or loss of accuracy of any measuring or control mechanism.
9.3. Devices must be designed and manufactured in such a way as to minimize the risks of
fire or explosion during normal use and in single fault condition. Particular attention must be
paid to devices whose intended use includes exposure to flammable substances or to
substances which could cause combustion.
10. Devices with a measuring function
10.1. Devices with a measuring function must be designed and manufactured in such a way
as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking
account of the intended purpose of the device. The limits of accuracy must be indicated by the
manufacturer.
10.2. The measurement, monitoring and display scale must be designed in line with
ergonomic principles, taking account of the intended purpose of the device.
10.3. The measurements made by devices with a measuring function must be expressed in
legal units conforming to the provisions of Act XLV of 1991 on measurement.
14 11. Protection against radiation
11.1. General
11.1.1. Devices shall be designed and manufactured in such a way that exposure of

patients, users and other persons to radiation shall be reduced as far as possible compatible
with the intended purpose, whilst not restricting the application of appropriate specified levels
for therapeutic and diagnostic purposes.
11.2. Intended radiation
11.2.1. Where devices are designed to emit hazardous levels of radiation necessary for a
specific medical purpose the benefit of which is considered to outweigh the risks inherent in
the emission, it must be possible for the user to control the emissions. Such devices shall be
designed and manufactured to ensure reproducibility and tolerance of relevant variable
parameters.
11.2.2. Where devices are intended to emit potentially hazardous, visible or invisible
radiation, they must be fitted, where practicable, with visual displays and/or audible warnings
of such emissions.
11.3. Unintended radiation
11.3.1. Devices shall be designed and manufactured in such a way that exposure of
patients, users and other persons to the emission of unintended, stray or scattered radiation is
reduced as far as possible.
11.4. Instructions
11.4.1. The operating instructions for devices emitting radiation must give detailed
information as to the nature of the emitted radiation, means of protecting the patient and the
user and on ways of avoiding misuse and of eliminating the risks inherent in installation.
11.5. Ionizing radiation
11.5.1. Devices intended to emit ionizing radiation must be designed and manufactured in
such a way as to ensure that, where practicable, the quantity, geometry and quality of
radiation emitted can be varied and controlled taking into account the intended use.
11.5.2. Devices emitting ionizing radiation intended for diagnostic radiology shall be
designed and manufactured in such a way as to achieve appropriate image and output quality

for the intended medical purpose whilst minimizing radiation exposure of the patient and user.
11.5.3. Devices emitting ionizing radiation, intended for therapeutic radiology shall be
designed and manufactured in such a way as to enable reliable monitoring and control of the
delivered dose, the beam type and energy and where appropriate the quality of radiation.
12. Requirements for medical devices connected to or equipped with an energy source
12.1. Devices incorporating electronic programmable systems must be designed to ensure
the repeatability, reliability and performance of these systems according to the intended use.
In the event of a single fault condition (in the system) appropriate means should be adopted to
eliminate or reduce as far as possible consequent risks.
12.2. Devices where the safety of the patients depends on an internal power supply must be
equipped with a means of determining the state of the power supply.
12.3. Devices where the safety of the patients depends on an external power supply must
include an alarm system to signal any power failure.
12.4. Devices intended to monitor one or more clinical parameters of a patient must be
equipped with appropriate alarm systems to alert the user of situations which could lead to
death or severe deterioration of the patient’ s state of health.
12.5. Devices must be designed and manufactured in such a way as to minimize the risks
15 of creating electromagnetic fields which could impair the operation of other devices or
equipment in the usual environment.
12.6. Protection against electrical risks
Devices must be designed and manufactured in such a way as to avoid, as far as possible,
the risk of accidental electric shocks during normal use and in single fault condition, provided
the devices are installed correctly.
12.7. Protection against mechanical and thermal risks
12.7.1. Devices must be designed and manufactured in such a way as to protect the patient
and user against mechanical risks connected with, for example, resistance, stability and
moving parts.

12.7.2. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.
12.7.3. Devices must be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.
12.7.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle must be designed and constructed in such a way as to minimize all possible risks.
12.7.5. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings must not attain potentially dangerous temperatures under normal use.
12.8. Protection against the risks posed to the patient by energy supplies or substances
12.8.1. Devices for supplying the patient with energy or substances must be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to guarantee the safety of the patient and of the user.
12.8.2. Devices must be fitted with the means of preventing or indicating any inadequacies in the flow-rate which could pose a danger.
Devices must incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy from an energy and/or substance source.
12.9. The function of the controls and indicators must be clearly specified on the devices.
Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.

13. Information supplied by the manufacturer
13.1. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.
This information comprises the details on the label and the data in the instructions for use.
As far as practicable and appropriate, the information needed to use the device safely must be set out on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information must be set out in the leaflet supplied with one or more devices.
Instructions for use must be included in the packaging for every device. By way of exception, no such instructions for use are needed for devices in Class I or IIa if they can be used safely without any such instructions.
13.2. Where appropriate, the information on the label should take the form of symbols.
16 Any symbol or identification colour used must conform to the harmonized standards. In areas for which no standards exist, the symbols and colours must be described in the documentation supplied with the device.
13.3. The label must bear the following particulars:
a) the name or trade name and address of the manufacturer. For devices imported into the EEA, in view of their distribution in the EEA, the label, or the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative;
b) the details strictly necessary for the user to identify the device and the contents of the packaging;
c) where appropriate, the word ‘STERILE’;
d) where appropriate, the batch code, preceded by the word ‘LOT, or the serial number;
e) where appropriate, an indication of the date by which the device should be used, in safety, expressed as the year and month;
f) where appropriate, an indication that the device is for single use:
g) if the device is custom-made, the words “rendelésre készült eszkz”

(‘custom-made
device’);
h) if the device is intended for clinical investigations, the words
” kizárólag klinikai
vizsgálatra” (‘exclusively for clinical investigations’);
i) any special storage and/or handling conditions;
j) any special operating instructions as required;
k) any warnings and/or precautions to take as required;
1) year of manufacture for active devices other than those covered by (e). This indication
may be included in the batch or serial number;
m) where applicable, method of sterilization;
n) in the case of a device within the meaning of Article 2 paragraph (2) d), an indication
that the device contains a human blood derivative.
13.4. If the intended purpose of the device is not obvious to the user, the manufacturer
must clearly state it on the label and in the instructions for use.
13.5. Wherever reasonable and practicable, the devices and detachable components must
be identified, where appropriate in terms of batches, to allow all appropriate action to detect
any potential risk posed by the devices and detachable components.
13.6. Where appropriate, the instructions for use must contain the following particulars:
a) the details referred to in Section 13.3. with the exception of (d) and (e);

b) the performances referred to in Section 3 and any undesirable side-effects;

c) if the device must be installed with or connected to other medical devices or equipment
in order to operate as required for its intended purpose, sufficient details of its characteristics
to identify the correct devices or equipment to use in order to obtain a safe combination;
d) all the information needed to verify whether the device is properly installed and can
operate correctly and safely, plus details of the nature and frequency of the maintenance and
calibration needed to ensure that the devices operate properly and safely at all times;
e) where appropriate, information to avoid certain risks in connection with implantation of
the device;
f) information regarding the risks of reciprocal interference posed by the

presence of the
device during specific investigations or treatment;
g) the necessary instructions in the event of damage to the sterile packaging and, where
appropriate, details of appropriate methods of resterilization;
h) if the device is reusable, information on the appropriate processes to allow reuse,
including cleaning, disinfection, packaging and, where appropriate, the method of sterilization
of the device to be resterilized, and any restriction on the number of reuses. Where devices are
17 supplied with the intention that they be sterilized before use, the instructions for cleaning and
sterilization must be such that, if correctly followed, the device will still comply with the
requirements in Section 1;
i) details of any further treatment or handling needed before the device can be used (for
example, sterilization, final assembly, etc.);
j) in the case of devices emitting radiation for medical purposes, details of the nature, type,
intensity and distribution of this radiation.
The instructions for use must also include details allowing the medical staff to brief the
patient on any contra-indications and any precautions to be taken. These details should cover
in particular:
k) precautions to be taken in the event of changes in the performance of the device;
l) precautions to be taken as regards exposure, in reasonably foreseeable environmental
conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure
or variations in pressure, acceleration, thermal ignition sources, etc.;
m) adequate information regarding the medicinal product or products which the device in
question is designed to administer, including any limitations in the choice of substances to be
delivered;
n) precautions to be taken against any special, unusual risks related to the disposal of the
device;
o) medicinal substances incorporated into the device as an integral part in accordance with

Section 7.4;
p) degree of accuracy claimed for devices with a measuring function.
13.7. Those listed in Sections 13.1-13.6 shall be available for the end user of the device in
Hungarian. The foreign language inscriptions located next to the concerned controls shall be
considered symbols if their meaning is explained in the instructions for use in detail.
14. Where conformity with the essential requirements must be based on clinical data, as in
Section I (6) of Part A, such data must be established in accordance with Annex 10.
B. In case of active implants:

I. General requirements
1. The devices must be designed and manufactured in such a way that, when implanted
under the conditions and for the purposes laid down, their use does not compromise the
clinical condition or the safety of the patients. They must not present any risk to the persons
implanting them or, where applicable, to other persons.
2. The devices must achieve the performances intended by the manufacturer. Be designed
and manufactured in such a way that they are suitable for one or more of the functions
referred to in Article 2 (a) as specified by him.
3. The characteristics and performances referred to in Sections 1 and 2 must not be
adversely affected to such a degree that the clinical condition and safety of the patients or, as
appropriate, of other persons are compromised during the lifetime of the device anticipated by
the manufacturer, where the device is subject to stresses which may occur during normal
conditions of use.
4. The devices must be designed, manufactured and packed in such a way that their
characteristics and performances are not adversely affected in the storage and transport
conditions laid down by the manufacturer (temperature, humidity, etc.).
5. Any undesirable side-effects must constitute an acceptable risk when weighed against
18 the performances intended.

II. Requirements regarding design and construction
6. The solutions adopted by the manufacturer for the design and construction of the devices
must conform to the general safety principles, taking account of the generally acknowledged
state of the art.
7. Implantable devices must be designed, manufactured and packed in a non-reusable pack
according to appropriate procedures to ensure they are sterile when placed on the market and,
in the storage and transport conditions stipulated by the manufacturer remain so until the
packaging is removed and they are implanted.
8. The device shall be of such design and construction that it shall remove or minimize as
far as is possible
a) the risk of injuries connected with its physical characteristics, including size specifics;
b) risks connected with the use of energy sources with particular reference, where
electricity is used, to insulation, leakage currents and overheating of the devices;
c) the risks related to the reasonably foreseeable environmental conditions (e.g. magnetic
fields, external electrical influences, electrostatic discharges, pressure, temperature or
variations in pressure and acceleration);
d) the risks related to medical interventions, especially with the employment of
defibrillators or high frequency surgical devices;
e) risks related to ionizing radiation originating from the radioactive materials complying
with the safety requirements specified by special legal regulations, contained in the device;
f) risks which may arise if maintenance or calibration are impossible, including
excessive increase of leakage currents,
ageing of the materials used,
excess heat generated by the device,
decreased accuracy of any measuring or control mechanism.
9. The device shall be designed and produced in such a way that characteristics and
performances referred to in the part titled I. General requirements could be guaranteed with

special regard to the following:
a) choice of the materials used, especially from the point of view of toxicity;
b) mutual compatibility between materials used, as well as the biological tissues, cells and
body fluids, taking account of the intended purpose of the device.
c) compatibility of the device with substances they are intended to administer;
d) the quality of the connections with special regard to safety;
e) reliability of the source of energy;
f) if appropriate, that they are leakproof;
g) proper functioning of the programming and control systems, including the software as
well.
10. Where a device incorporates as its integral part a substance which, if used separately,
may be considered to be a medicinal product and which is liable to get into the physiological
processes with action ancillary to that of the device, the safety, quality and usefulness of the
substance must be verified, taking account of the intended purpose of the device, by analogy
with the appropriate methods specified by the legal regulation on the registration of
medicines.
11. Devices and their detachable components must be identified to allow any necessary
measure to be taken following the discovery of a potential risk in connection with the devices
and their component parts.
19 12. Each device shall bear the code by which the device (especially the type and the year of
manufacturing) and its manufacturer can be unambiguously identified. This code shall be
legible if necessary without surgical intervention.
13. When a device or its accessories bear instructions required for the operation of the
device or indicate operating or adjustment parameters, by means of a visual system, such
information must be understandable for the user and if appropriate, for the patient.
14. Every device must bear, legibly and indelibly the following particulars, where
appropriate in the form of generally recognized symbols:
14.1. On the sterile packing:

a) the method of sterilization
b) a marking enabling to recognize sterility on the given packing;
c) the name and address of the manufacturer;
d) the name of the device;
e) if the device is intended for clinical investigations, the words
“kizárólag klinikai
vizsgálatok céljára” (“exclusively for clinical investigations”);
f) if the device is custom-made, the words ”rendelésre készült eszkz”
(“custom-made
device”);
g) reference to the fact that the implant is sterile;
h) the month and year of manufacturing;
i) the expiry date of the safe implantation of the device.
14.2. On the sales packaging:
a) the name and address of the manufacturer;
b) the name of the device;
c) the intended purpose of the device;
d) the relevant characteristics taking account of the intended use;
e) if the device is intended for clinical investigations, the words
”kizárólag klinikai
vizsgálatok céljára” (”exclusively for clinical investigations”);
f) if the device is custom-made, the words ”rendelésre készült”
(”custom-made”);
g) the reference to the fact that the implant is in a sterile condition;
h) the month and year of manufacturing;
i) the expiry date of the safe implantation of the device;
j) conditions of transport and storage of the device.
15. When placed on the market, each device must be accompanied by instructions
for use
giving the following particulars:
a) the year of authorization to affix the CE mark;
b) the details referred to in Sections 14.1 and 14.2 with the exception of
those referred to in
(h) and (i);
c) the performances referred to in Section 2, furthermore any undesirable
side-effects;
d) information allowing the physician to select a suitable device and the
corresponding
software and accessories;
e) information allowing the physician and where appropriate, the patient to
use the device,
its accessories and software correctly, as well as information on the nature,
scope and times
for operating controls and trials and, where appropriate, maintenance

measures;
f) information allowing, if appropriate, certain risks in connection with implantation of the
device to be avoided;
g) information regarding the risk of reciprocal interference in connection with the presence
of the device during certain special investigations or treatments. Reciprocal interference
means adverse effects on the device caused by instruments present at the time of
investigations or the treatment, and vice versa.
20 h) the necessary instructions in the event of the sterile pack being damaged and, where
appropriate, details of appropriate methods of resterilization;
i) where appropriate warning relating to the fact that the device can be reused only if it is
reconditioned under the responsibility of the manufacturer to comply with the essential
requirements.
Furthermore the instructions for use shall contain particulars allowing the physician to
inform the patient on the contraindication and the safety measure to be taken. These should
cover in particular:
j) information allowing the lifetime of the energy source to be established;
k) precautions to be taken should changes occur in the device' s performance;
1) precautions to be taken as regards exposure, in reasonably foreseeable environmental
conditions, to magnetic fields, external electrical influences, electrostatic discharge, pressure
or variations in pressure, acceleration;
m) appropriate information relating to medicines the administering of which is the purpose
of the device.
Those listed in Sections 13. 15. shall be available for the end user of the device in
Hungarian.
16. Confirmation that under circumstances of use according to the purpose laid down by
the manufacturer the instrument meets, regarding its characteristics and performance, the
requirement referred to in "I. General requirements", as well as the evaluation of the side or
undesired effects shall be based on the clinical data specified in Annex 10.
ANNEX 2

to Decree of the Minister of Health No. 16/2006. (III. 27.)EüM

Full quality assurance system

A. In case of classified devices:
1. The manufacturer must ensure application of the quality system approved for the design,
manufacture and final inspection of the products concerned, as specified in Section 3 and is
subject to audit as laid down in Sections 3.3 and 4 and to surveillance as specified in Section
5.
2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the
obligations imposed by Section 1 ensures and declares that the products concerned meet the
provisions of this Decree which apply to them.
The manufacturer must affix the CE marking in accordance with Article 3 and draw up a
written declaration of conformity. This declaration must cover a given number of the products
manufactured and be kept by the manufacturer.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system with
a notified body. The application must include:
a) the name and address of the manufacturer and any additional manufacturing site covered
by the quality system,
b) all the relevant information on the product or product category covered by the
procedure,
c) a written declaration that no application has been lodged with any other notified body
for the same product-related quality system,
d) the documentation on the quality system,
e) an undertaking by the manufacturer to fulfil the obligations imposed by the quality
system approved,
21 f) an undertaking by the manufacturer to keep the approved quality system adequate and
efficacious,
g) an undertaking by the manufacturer to institute and keep up to date a systematic

procedure to review experience gained from devices in the post-production phase and to
implement appropriate means to apply any necessary corrective action. This undertaking must
include an obligation for the manufacturer to notify the competent authorities of the incidents
immediately on learning of them, according to Article 14.
3.2. Application of the quality system must ensure that the products conform to the
provisions of this Decree which apply to them at every stage, from design to final inspection.
All the elements, requirements and provisions adopted by the manufacturer for his quality
system must be documented in a systematic and orderly manner in the form of written
policies and procedures such as quality programmes, quality plans, quality manuals and
quality records. It shall include in particularly an adequate description of:
a) the manufacturer’ s quality objectives;
b) the organization of the business and in particular:
- the organizational structures, the responsibilities of the managerial staff and their
organizational authority where quality of design and manufacture of the products is
concerned,
- the methods of monitoring the efficient operation of the quality system and in particular
its ability to achieve the desired quality of design and of product, including control of
products which fail to conform;
c) the procedures for monitoring and verifying the design of the products and in particular:
- a general description of the product, including any variants planned,
- the design specifications, including the standards which will be applied and the results of
the risk analysis; and also a description of the solutions adopted to fulfil the essential
requirements which apply to the products if the relevant harmonized standards referred to in
Article 2 are not applied in full,
- the techniques used to control and verify the design and the processes and systematic
measures which will be used when the products are being designed,
- if the device is to be connected to other device(s) in order to operate as intended, proof

must be provided that it conforms to the essential requirements when connected to any such
device(s) having the characteristics specified by the manufacturer,
- a statement indicating whether or not the device incorporates, as an integral part, a
substance or a human blood derivative referred to in Section 7.4 in Part A of Annex 1 and the
data on the tests conducted in this connection required to assess the safety, quality and
usefulness of that substance or human blood derivative, taking account of the intended
purpose of the device,
- the clinical data referred to in Annex 10,
- the draft label and, where appropriate, instructions for use;
d) the inspection and quality assurance techniques at the manufacturing stage and in
particular:
- the processes and procedures which will be used, particularly as regards sterilization,
purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings,
specifications or other relevant documents at every stage of manufacture;
e) the appropriate tests and trials which will be carried out before, during and after
manufacture, the frequency with which they will take place, and the test equipment used; it
must be possible to trace back the calibration of the test equipment adequately.
3.3. The notified body must audit the quality system to determine whether it meets the
requirements referred to in Section 3.2. It must presume that, quality systems which
22 implement the relevant harmonized standards conform to these requirements. The assessment
team must include at least one member with past experience of assessments of the technology
concerned. The assessment procedure must include an inspection on the manufacturer’ s
premises and, in duly substantiated cases, on the premises of the manufacturer’ s suppliers
and/or subcontractors to inspect the manufacturing processes. The decision is notified to the
manufacturer. It must contain the conclusions of the inspection and a reasoned

assessment.
3.4. The manufacturer must inform the notified body which approved the quality system of
any plan for substantial changes to the quality system or the product-range covered. The
notified body must assess the changes proposed and verify whether after these changes the
quality system still meets the requirements referred to in Section 3.2. It must notify the
manufacturer of its decision. This decision must contain the conclusions of the inspection and
a reasoned assessment.
4. Examination of the design of the product
4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with
the notified body an application for examination of the design dossier relating to the product
which he plans to manufacture and which falls into the category referred to in Section 3.1.
4.2. The application must include the design, manufacture and performances of the product
in question. It must include the documents needed to assess whether the product conforms to
the requirements of this Decree, as referred to in Section 3.2 (c).
4.3. The notified body must examine the application and if the product conforms to the
relevant provisions of this Decree, issue the applicant with a design-examination certificate.
The notified body may require the application to be completed by further tests or proof to
allow assessment of conformity with the requirements of the Decree. The certificate must
contain the conclusions of the examination, the conditions of validity, the data needed for
identification of the approved design, where appropriate, a description of the intended purpose
of the product.
In the case of devices referred to in Annex 1, Part A, Section II. 7.4, first subparagraph, the
notified body shall, as regards the aspects referred to in that section, consult the competent
body authorized to register medicines before taking a decision. The notified body will give
due consideration to the views expressed in this consultation when making its decision. It will

convey its final decision to the competent body authorized to register medicines. In the case
of devices referred to in Annex 1, Part A, Section II. 7.4, second subparagraph, the scientific
opinion of the EMEA must be included in the documentation concerning the device. The
notified body will give due consideration to the opinion of the EMEA when making its
decision. The notified body may not deliver the certificate if the EMEA’ s scientific opinion is
unfavourable. It will convey its final decision to the EMEA.
4.4. Changes to the approved design must receive further approval from the notified body
which issued the design-examination certificate wherever the changes could affect conformity
with the essential requirements of the Decree or with the conditions prescribed for use of the
product. The applicant shall inform the notified body which issued the design-examination
certificate of any such changes made to the approved design. This additional approval must
take the form of a supplement to the design-examination certificate.
5. Surveillance
5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations
imposed by the approved quality system.
5.2. The manufacturer must authorize the notified body to carry out all the necessary
inspections and supply it with all relevant information, in particular:
a) the documentation on the quality system,
b) the data stipulated in the part of the quality system relating to design, such as the results
of analyses, calculation, tests, etc.,
23 c) the data stipulated in the part of the quality system relating to manufacture, such as
inspection reports and test data, calibration data, qualification reports of the personnel
concerned, etc.
5.3. The notified body must periodically carry out appropriate inspections and assessments
to make sure that the manufacturer applies the approved quality system and must supply the
manufacturer with an assessment report.
5.4. In addition, the notified body may pay unannounced visits to the

manufacturer. At the
time of such visits, the notified body may, where necessary, carry out or ask for tests in order
to check that the quality system is working properly. It must provide the manufacturer with an
inspection report and, if a test has been carried out, with a test report.
6. Administrative provisions
6.1. The manufacturer must, for a period ending at least five years after the last product has
been manufactured, keep at the disposal of the authorities:
a) the declaration of conformity,
b) the documentation referred to in the second indent of Section 3.2.(c),
c) the changes referred to in Section 3.4,
d) the documentation referred to in Section 4.2, and
e) the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4,
5.3 and 5.4.
6.2. In respect of devices subject to the procedure in Section 4, when the manufacturer
does not have a registered place of business in EEA Member State the obligation to keep
available the technical documentation shall fall to the authorised representative as referred to
in Article 2(1m).
7. Application to devices in Classes IIa and IIb
In line with Article 6 (2) and (3), this Annex may apply to products in Classes IIa and IIb.
Section 4, however, does not apply.
8. Application to the devices referred to Article 2 (2d)
Upon completing the manufacture of each batch of devices referred to in Article 2 (2d), the
manufacturer shall inform the notified body of the release of the batch of devices and send to
it the official certificate concerning the release of the batch of human blood derivative used in
the device, issued by a laboratory according to Annex 1, Part A, Section II. 7.4., third
subparagraph.

B. In case of active implants:
1. The manufacturer must ensure application of the quality system approved for the design,
manufacture and final inspection of the products concerned, as specified in Section 3 and 4
and to surveillance as specified in Section 5.

2. The declaration of conformity is the procedure whereby the manufacturer who fulfils the
obligations imposed by Section 1 ensures and declares that the products concerned meet the
provisions of this Decree which apply to them.
The manufacturer or the authorised representative must affix the CE marking in accordance with Article 3 and draw up a written declaration of conformity. This declaration
may cover one device or several of them and be kept by the manufacturer or the authorised
representative.
The CE mark shall be accompanied by the identification number of the notified body
responsible.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system with
a notified body. The application must include:
a) all the relevant information on the product category to be produced
24 b) the documentation on the quality system,
c) an undertaking by the manufacturer to fulfil the obligations imposed by the quality
system approved,
d) an undertaking by the manufacturer to keep the approved quality system adequate and
efficacious,
e) an undertaking by the manufacturer to institute and keep up to date a systematic
procedure to review experience gained from devices in the post-production phase. This
undertaking must include an obligation for the manufacturer to notify the incidents
immediately on learning of them, according to Article 14,
3.2. Application of the quality system must ensure that the products conform to the
provisions of this Decree which apply to them at every stage, from design to final inspection.
All the elements, requirements and provisions adopted by the manufacturer for his quality
system must be documented in a systematic and orderly manner. This documentation of the
quality system must ensure the unified interpretation of written policies and procedures such

as in the form of quality programmes, quality plans, quality manuals and quality records.
It shall include in particularly an adequate description of:
a) the manufacturer' s quality objectives;
b) the organization of the business and in particular:
- the organizational structures, the responsibilities of the managerial staff and their
organizational authority where quality of design and manufacture of the products is
concerned,
- the methods of monitoring the efficient operation of the quality system and in particular
its ability to achieve the desired quality of design and of product, including control of
products which fail to conform;
c) the procedures for monitoring and verifying the design of the products and in particular:
- the design specifications, including the standards which will be applied and also a
description of the solutions adopted to fulfil the essential requirements which apply to the
products if the relevant standards referred to in Article 2 are not applied or not applied in full,
- the techniques used to control and verify the design and the processes and systematic
measures which will be used when the products are being designed,
d) the inspection and quality assurance techniques at the manufacturing stage and in
particular:
- the processes and procedures which will be used, particularly as regards sterilization,
purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings,
specifications or other relevant documents at every stage of manufacture;
e) the appropriate tests and trials which will be carried out before, during and after
manufacture, the frequency with which they will take place, and the test equipment used.
3.3. The notified body must audit the quality system to determine whether it meets the
requirements referred to in Section 3.2. It must presume that, quality systems which
implement the relevant harmonized standards conform to these requirements.
The assessment team must include at least one member with past experience of

assessments of the technology concerned. The assessment procedure must include an
inspection on the manufacturer’ s premises.
The decision of the assessment is notified to the manufacturer. It must contain the
conclusions of the inspection and a reasoned assessment.
3.4. The manufacturer must inform the notified body which approved the quality system of
any plan for changes to the quality system or the product-range covered. The notified body
must assess the changes proposed and verify whether after these changes the quality system
still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its
25 decision. This decision must contain the conclusions of the inspection and a reasoned
assessment.
4. Examination of the design of the product
4.1. In addition to the obligations imposed by Section 3, the manufacturer must lodge with
the notified body an application for examination of the design dossier relating to the product
which he plans to manufacture and which falls into the category referred to in Section 3.1.
4.2. The application must describe the design, manufacture and performances of the
product in question. It must include the documents needed to assess whether the product
conforms to the requirements of this Decree.
The application must include:
a) the design specifications, including the standards which will be applied; the appropriate
certification of the competence of these standards especially the standards referred to in
Article 2 are not applied in full. This certificate must include the results of the conformity
examination performed by the manufacturer or performed under his responsibility;
b) information if the device incorporates as an integral part a substance referred to in
Annex 1, Part B, Section II. 10 which is liable to act upon the body with action ancillary to
that of the device and may result in getting in the physiological processes, together with the

relating data on the appropriate tests performed. The results of the relevant examinations must
be enclosed;
c) the clinical data referred to in Annex 10;
d) the draft of the instructions for use.
4.3. The notified body must examine the application and if the product conforms to the
relevant provisions of this Decree, issue the applicant with a design-examination certificate.
The notified body may require the application to be completed by further tests or proof to
allow assessment of conformity with the requirements of the Decree. The certificate must
contain the conclusions of the examination, the conditions of validity, the data needed for
identification of the approved design, where appropriate, a description of the intended purpose
of the product.
4.4. The manufacturer or the applicant shall inform the notified body which issued the
design-examination certificate of any changes made to the approved design. Such changes
must receive further approval from the notified body which issued the design-examination
certificate wherever the changes could affect conformity with the essential requirements of
the Decree or with the conditions prescribed for use of the product. This additional approval
must take the form of a supplement to the design-examination certificate.
5. Surveillance
5.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations
imposed by the approved quality system.
5.2. The manufacturer must authorize the notified body to carry out all the necessary
inspections and supply it with all relevant information, in particular:
a) the documentation on the quality system,
b) the data stipulated in the part of the quality system relating to design, such as the results
of analyses, calculation, tests, etc.,
c) the data stipulated in the part of the quality system relating to manufacture, such as
inspection reports and test data, calibration data, qualification reports of the personnel
concerned, etc.

5.3. The notified body must periodically carry out appropriate inspections and assessments
to make sure that the manufacturer applies the approved quality system and must supply the
26 manufacturer with an assessment report.
5.4. In addition, the notified body may pay unannounced visits to the manufacturer. It must
provide the manufacturer with an inspection report.
6. Administrative provisions
6.1. The manufacturer must, for a period ending at least five years after the last product has
been manufactured, keep at the disposal of the authorities:
a) the declaration of conformity,
b) the documentation referred to in Section 3.1.(b),
c) the changes referred to in Section 3.4,
d) he documentation referred to in Section 4.2, and
e) the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 5.3
and 5.4.
6.2. When the manufacturer does not have a registered place of business in EEA Member
State, the obligation to keep available the technical documentation shall fall to the authorised
representative as referred to in Article 2(1m).
ANNEX 3
tof Decree of the Minister of Health No. 16/2006. (III. 27.)EüM

Type-examination
A. In case of classified devices:
1. Type-examination is the procedure whereby a notified body ascertains and certifies that
a representative sample of the production covered fulfils the relevant provisions of this
Decree. Type-examination is lodged by the manufacturer or its authorized representative at a
notified body.
2. The application includes:
a) the name and address of the manufacturer and the name and address of the authorized
representative if the application is lodged by the representative,
b) the documentation described in Section 3 needed to assess the conformity of the
representative sample of the production in question (hereinafter referred to as the type) with

the requirements of this Decree. The applicant must make a type available to the notified
body. The notified body may request other samples as necessary,
c) a written declaration that no application has been lodged with any other notified body
for the same type.
3. The documentation must allow an understanding of the design, the manufacture and the
performances of the product and must contain the following items in particular:
a) a general description of the type, including any variants planned,
b) design drawings, methods of manufacture envisaged, in particular as regards

sterilization, and diagrams of components, sub-assemblies, circuits, etc.,
c) the descriptions and explanations necessary to understand the abovementioned drawings
and diagrams and the operation of the product,
d) a list of the standards referred to in Article 2, applied in full or in part, and descriptions
of the solutions adopted to meet the essential requirements if the standards referred to in
Article 2 have not been applied in full,
e) the results of the design calculations, risk analysis, investigations, technical tests, etc.
carried out,
f) a statement indicating whether or not the device incorporates, as an integral part, a
substance or human blood derivative as referred to in Section II. 7.4 of Part A of Annex 1, and
the data on the tests conducted in this connection which are required to assess the safety,
27 quality and usefulness of the substance or human blood derivative, taking account of the
intended purpose of the device,
g) the clinical data referred to in Annex 10,
h) the draft label and, where appropriate, instructions for use.
4. The notified body must:
4.1. examine and assess the documentation and verify that the type has been manufactured
in conformity with that documentation; it must also record the items designed in conformity
with the applicable provisions of the standards referred to in Article 2, as well as the items not
designed on the basis of the relevant provisions of the above mentioned standards;

4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify
whether the solutions adopted by the manufacturer meet the essential requirements of Annex 1
of this Decree if the standards referred to in Article 2 have not been applied; if the device is to
be connected to other device(s) in order to operate as intended, proof must be provided that it
conforms to the essential requirements when connected to any such device(s) having the
characteristics specified by the manufacturer;
4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify
whether, if the manufacturer has chosen to apply the relevant standards, these have actually
been applied;
4.4. agree with the applicant on the place where the necessary inspections and tests will be
carried out.
5. If the type conforms to the provisions of this Decree, the notified body issues the
applicant with a type-examination certificate. The certificate must contain the name and
address of the manufacturer, the conclusions of the inspection, the conditions of validity and
the data needed for identification of the type approved. The relevant parts of the
documentation must be annexed to the certificate and a copy kept by the notified body. In the
case of devices referred to in Annex 1, Part A, Section II. 7.4, first subparagraph, the notified
body shall, as regards the aspects referred to in that section , consult the competent body
authorized to register medicines before taking a decision. The notified body will give due
consideration to the views expressed in this consultation when making its decision. It will
convey its final decision to the competent body authorized to register medicines. In the case
of devices referred to in Annex 1, Part A, Section II. 7.4, second subparagraph, the scientific
opinion of the EMEA must be included in the documentation concerning the device. The
notified body will give due consideration to the opinion of the EMEA when

making its
decision. The notified body may not deliver the certificate if the EMEA' s scientific opinion is
unfavourable. It will convey its final decision to the EMEA.
6. The applicant must inform the notified body which issued the type-examination
certificate of any significant change made to the approved product. Changes to the approved
product must receive further approval from the notified body which issued the typeexamination certificate wherever the changes may affect conformity with the essential
requirements or with the conditions prescribed for use of the product. This new approval
must, where appropriate, take the form of a supplement to the initial type-examination
certificate.
7. Administrative provisions
7.1. Other notified bodies may obtain a copy of the type-examination certificates and/or the
supplements thereto. The annexes to the certificates must be made available to other notified
bodies on reasoned application, after the manufacturer has been informed.
7.2. The manufacturer or his authorized representative must keep with the technical
documentation copies of type-examination certificates and their supplements for a period
ending at least five years after the last device has been manufactured.
7.3. When the manufacturer does not have a registered place of business in EEA Member
28 State, the obligation to keep available the technical documentation shall fall to the authorised
representative referred to in Article 2(1m).

B. In case of active implants:
1. Type-examination is the procedure whereby a notified body ascertains and certifies that
a representative sample of the production covered fulfils the relevant provisions of this
Decree.
2. Type-examination is lodged by the manufacturer or its authorized representative referred
to in Article 10, Section (2) with a notified body. The application includes:
a) the name and address of the manufacturer and the name and address of the authorized
representative if the application is lodged by the authorised representative,

b) a written declaration that no application has been lodged with any other notified body
for the same type,
c) the documentation described in Section 3 needed to assess the conformity of the
representative sample of the production in question (hereinafter referred to as the type), with
the requirements of this Decree. The applicant must make a type available to the notified
body. The notified body may request other samples as necessary.
3. The documentation must allow an understanding of the design, the manufacture and the
performances of the product and must contain the following items in particular:
a) a general description of the type,
b) design drawings, methods of manufacture envisaged, in particular as regards

sterilization, and diagrams of components, sub-assemblies, circuits, etc.,
c) the descriptions and explanations necessary to understand the above mentioned
drawings and diagrams and the operation of the product,
d) a list of the standards referred to in Article 2, applied in full or in part, and descriptions
of the solutions adopted to meet the essential requirements if the standards referred to in
Article 2 have not been applied in full,
e) the results of the design calculations, risk analysis, investigations, technical tests, etc.
carried out,
f) a statement indicating whether or not the device incorporates, as an integral part, a
substance as referred to in Annex 1, Part B, Section II. 10, which is liable to act upon the
body with action ancillary to that of the device and may result in getting in the physiological
processes, together with the relating data on the appropriate tests performed. Data on the tests
conducted in this connection must be annexed,
g) the clinical data referred to in Annex 10,
h) the draft of the instructions for use.
4. The notified body must in the course of the type-examination:
4.1. examine and assess the documentation and verify that the type has been manufactured
in conformity with that documentation; it must also record the items designed

in conformity
with the applicable provisions of the standards referred to in Article 2, as well as the items not
designed on the basis of the relevant provisions of the above mentioned standards;
4.2. carry out or arrange for the appropriate inspections and the tests necessary to verify
whether the solutions adopted by the manufacturer meet the essential requirements of Annex 1
of this Decree if the standards referred to in Article 2 have not been applied in full;
4.3. carry out or arrange for the appropriate inspections and the tests necessary to verify
whether, if the manufacturer has chosen to apply the relevant standards, these have actually
been applied;
4.4. agree with the applicant on the place where the necessary inspections and tests will be
carried out.
5. If the type conforms to the provisions of this Decree, the notified body issues the
29 applicant with a type-examination certificate. The certificate must contain the name and
address of the manufacturer, the conclusions of the inspection, the conditions of validity and
the data needed for identification of the type approved. The relevant parts of the
documentation must be annexed to the certificate and a copy kept by the notified body.
6. The applicant must inform the notified body which issued the type-examination
certificate of any significant change made to the approved product.
Changes to the approved product must receive further approval from the notified body
which issued the type-examination certificate wherever the changes may affect conformity
with the essential requirements or with the conditions prescribed for use of the product. This
new approval must, where appropriate, take the form of a supplement to the initial typeexamination certificate.
7. Administrative provisions
7.1. Other notified bodies may obtain copies of the type-examination certificates and/or the
supplements thereto. The annexes to the certificates must be made available to other notified

bodies on reasoned application, after the manufacturer has been informed.
7.2. The manufacturer or his authorized representative must keep with the technical documentation copies of type-examination certificates and their supplements for a period ending at least five years after the last device has been manufactured.
7.3. When the manufacturer does not have a registered place of business in EEA Member State, the obligation to keep available the technical documentation shall fall to the authorised representative referred to in Article 2(1m).
ANNEX 4
to Decree of the Minister of Health No.16/2006. (III. 27.) EüM

Verification
A. In case of classified devices
1. Verification is the procedure whereby the manufacturer or his authorized representative ensures and declares that the products which have been subject to the procedure set out in Section 4 conform to the type described in the type-examination certificate and meet the requirements of this Decree which apply to them.
2. The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which conform to the type described in the type-examination certificate and to the requirements of the Decree which apply to them. Before the start of manufacture, the manufacturer must prepare documents defining the manufacturing process, in particular as regards sterilization where necessary, together with all the routine, preestablished provisions to be implemented to ensure homogeneous production and, where appropriate, conformity of the products with the type described in the type-examination certificate and with the requirements of this Decree which apply to them. The manufacturer must affix the CE marking referred to in Article 3 and draw up a declaration of conformity. In addition, for products placed on the market in sterile condition, and only for those aspects of the manufacturing process designed to secure and maintain sterility, the manufacturer must

apply the provisions of Annex 5, Sections 3 and 4.
3. The manufacturer must undertake to institute and keep up to date a systematic procedure
to review experience gained from devices in the post-production phase and to implement
appropriate means to apply any necessary corrective action. This undertaking obliges the
manufacturer also to report events immediately according to Article 14.
4. The notified body must carry out the appropriate examinations and tests in order to
30 verify the conformity of the product with the requirements of this Decree either by examining
and testing every product as specified in Section 5 or by examining and testing products on a
statistical basis as specified in Section 6, as the manufacturer decides. The aforementioned
checks do not apply to those aspects of the manufacturing process designed to secure sterility.
5. Verification by examination and testing of every product (examination of pieces)
5.1. Every product is examined individually and the appropriate tests defined in the
relevant standard(s) referred to in Article 2 or equivalent tests must be carried out in order to
verify, where appropriate, the conformity of the products with the type described in the typeexamination certificate and with the requirements of this Decree which apply to them.
5.2. The notified body must affix, or have affixed its identification number to each
approved product and must draw up a written certificate of conformity relating to the tests
carried out.
6. Statistical verification
6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.
6.2. A random sample is taken from each batch. The products which make up the sample
are examined individually and the appropriate tests defined in the relevant standard(s) referred
to in Article 2 or equivalent tests must be carried out to verify, where appropriate, the
conformity of the products with the type described in the type-examination certificate and
with the requirements of this Decree which apply to them in order to determine whether to

accept or reject the batch.
6.3. Statistical control of products will be based on attributes, entailing a sampling system
ensuring a limit quality corresponding to a probability of acceptance of 5%, with a nonconformity percentage of between 3 and 7 %.
6.4. If the batch is accepted, the notified body affixes or has affixed its identification
number to each product and draws up a written certificate of conformity relating to the tests
carried out. All products in the batch may be put on the market except any in the sample
which failed to conform.
If a batch is rejected, the competent notified body must take appropriate measures to
prevent the batch from being placed on the market. In the event of frequent rejection of
batches, the notified body may suspend the statistical verification.
The manufacturer may, on the responsibility of the notified body, affix the notified body' s
identification number during the manufacturing process.
7. Administrative provisions
The manufacturer or his authorized representative must, for a period ending at least five
years after the last product has been manufactured, make available to the Authority:
a) the declaration of conformity,
b) the documentation referred to in Section 2,
c) the certificates referred to in Sections 5.2 and 6.4,
d) where appropriate, the type-examination certificate referred to Annex 3
8. Application to devices in Class IIa
In line with Article 6 (2), this Annex may apply to products in Class IIa, subject to the
following exemptions:
8.1. in derogation from Sections 1 and 2, by virtue of the declaration of conformity the
manufacturer ensures and declares that the products in Class IIa are manufactured in
conformity with the technical documentation referred to in Section 3 of Annex 7 and meet the
requirements of this Decree which apply to them;
8.2. in derogation from Sections 1, 2, 5 and 6, the verifications conducted by the notified
body are intended to confirm the conformity of the products in Class IIa with the technical

documentation referred to in Section 3 of Annex 7.
31 9. Application to devices referred to in Article 2 (2 d)
In the case of Section 5, upon completing the manufacture of each batch of devices referred to
in Article 2 (2 d), and in the case of verification under Section 6, the manufacturer shall
inform the notified body of this batch of devices and send to it the official certificate
concerning the release of the batch of human blood derivative used in the device issued by the
laboratory in accordance with Annex 1, Point A, Section II. 7.4, third subparagraph.

B. In case of active implants:
1. Verification is the procedure whereby the manufacturer or his authorized representative
ensures and declares that the products which have been subject to the procedure set out in
Section 3 conform to the type described in the type-examination certificate and meet the
requirements of this Decree which apply to them.
2. The manufacturer must take all the measures necessary to ensure that the manufacturing
process produces products which conform to the type described in the type-examination
certificate and to the requirements of the Decree which apply to them. The manufacturer must
affix the CE marking referred to in Article 3 and draw up a declaration of conformity.
3. Before the start of manufacture, the manufacturer must prepare documents defining the
manufacturing process, in particular as regards sterilization where necessary, together with all
the routine, pre-established provisions to be implemented to ensure homogeneous production
and, where appropriate, conformity of the products with the type described in the typeexamination certificate and with the requirements of this Decree which apply to them.
4. The manufacturer must undertake to institute and keep up to date a systematic procedure
to review experience gained from devices in the post-production phase and to implement
appropriate means to apply any necessary corrective action. This undertaking obliges the
manufacturer also to report events immediately according to Article 14.

5. The notified body must carry out the appropriate examinations and tests on statistical basis according to Section 6 in order to verify the conformity of the product with the requirements of this Decree. The manufacturer must authorize the notified body to assess the efficacy of the means implemented according to Section 2 by actual product audit.

6. Statistical verification

6.1. The manufacturer must manufacture and present the products in the form of homogeneous batches and must implement all necessary means in order to ensure that the production process ensures the homogenity of all batches produced.

6.2. A random sample is taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standard(s) referred to in Article 2 or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of this Decree which apply to them in order to determine whether to accept or reject the batch.

6.3. Statistical control of products will be based on attributes, entailing a sampling system according to the following characteristics:

- a level of quality corresponding to a probability of acceptance of 95 %, with a nonconformity percentage of between 0.29 and 1 %;
- a limit quality corresponding to a probability of acceptance of 5 %, with a non-conformity percentage of between 3 and 7 %.

6.4. If the batch is accepted, the notified body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the competent notified body must take appropriate measures to

 prevent the batch from being placed on the market. In the event of frequent rejection of

batches, the notified body may suspend the statistical verification.
The manufacturer may, on the responsibility of the notified body, affix the notified body' s
identification number during the manufacturing process.
6.5. The manufacturer or its authorized representative must be able to present the
conformity certificate issued by the notified body at request.
ANNEX 5
to Decree of the Minister of Health No.16/2006. (III. 27.) EüM

Production quality assurance
A. In case of classified devices:
1. The manufacturer must ensure application of the quality system approved for the
manufacture of the products concerned and carry out the final inspection, as specified in
Section 3, and is subject to the surveillance referred to in Section 4.
2. The declaration of conformity is the part of the procedure whereby the manufacturer
who fulfils the obligations imposed by Section 1 ensures and declares that the products
concerned conform to the type described in the type-examination certificate and meets the
provisions of this Decree which apply to them.
The manufacturer must affix the CE marking in accordance with Article 3 and draw up a
written declaration of conformity. This declaration must cover a given number of identified
specimens of the products manufactured and must be kept by the manufacturer.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system with
a notified body. The application must include:
a) the name and address of the manufacturer,
b) all the relevant information on the product or product category covered by the
procedure,
c) a written declaration that no application has been lodged with any other notified body
for the same products,
d) the documentation on the quality system,
e) an undertaking to fulfil the obligations imposed by the quality system is approved,
f) an undertaking to maintain the practicability and effectiveness of the approved quality

system,
g) where appropriate, the technical documentation on the types approved and a copy of the
type-examination certificates,
h) an undertaking by the manufacturer to notify of the incidents immediately on learning of
them according to Article 14.
3.2. Application of the quality system must ensure that the products conform to the type
described in the type-examination certificate. All the elements, requirements and provisions
adopted by the manufacturer for his quality system must be documented in a systematic and
orderly manner in the form of written policy statements and procedures. This quality system
documentation must permit uniform interpretation of the quality policy and procedures such
as quality programmes, plans, manuals and records. It must include in particular an adequate
description of:
a) the manufacturer’ s quality objectives;
b) the organization of the business and in particular:
- the organizational structures, the responsibilities of the managerial staff and their
organizational authority where manufacture of the products is concerned,
33 - the methods of monitoring the efficient operation of the quality system and in particular
its ability to achieve the desired quality of product, including control of products which fail to
conform;
c) the inspection and quality assurance techniques at the manufacturing stage and in
particular:
- the processes and procedures which will be used, particularly as regards sterilization,
purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings,
specifications or other relevant documents at every stage of manufacture;
d) the appropriate tests and trials to be carried out before, during and after manufacture, the
frequency with which they will take place, and the test equipment used; it must be possible
adequately to trace back the calibration of the test equipment.

3.3. The notified body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant harmonized standards conform to these requirements. The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an inspection on the manufacturer’ s premises and, in duly substantiated cases, on the premises of the manufacturer’ s suppliers to inspect the manufacturing processes. The decision must be notified to the manufacturer after the final inspection and contain the conclusions of the inspection and a reasoned assessment.

3.4 The manufacturer must inform the notified body which approved the quality system of any plan for substantial changes to the quality system. The notified body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations imposed by the approved quality system.

4.2. The manufacturer authorizes the notified body to carry out all the necessary inspections and must supply it with all relevant information, in particular:

a) the documentation on the quality system,

b) the data stipulated in the part of the quality system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.

4.3. The notified body must periodically carry out appropriate inspections and assessments to make sure that the manufacturer applies the approved quality system and supply the manufacturer with an assessment report.

4.4. The notified body may pay unannounced visits to the manufacturer. At the time of

such visits the notified body may, where necessary, carry out or ask for tests in order to check
that the quality system is working properly. It must provide the manufacturer with an
inspection report and, if a test has been carried out, with a test report.
5. Administrative provisions
5.1. The manufacturer must, for a period ending at least five years after the last product has
been manufactured, make available to the Authority:
a) the declaration of conformity,
b) the documentation referred to in Section 3.1.(d),
c) the changes referred to in Section 3.4,
d) the documentation referred to in Section 3.1.(g),
e) the decisions and reports from the notified body as referred to in Sections 4.3 and 4.4,
f) where appropriate, the type-examination certificate referred to in Annex 3.

34 6. Application to devices in Class IIa
In line with Article 6 (2), this Annex may apply to products in Class IIa, subject to the
following exemption:
6.1. in derogation from Sections 2, 3.1 and 3.2, by virtue of the declaration of conformity
the manufacturer ensures and declares that the products in Class IIa are manufactured in
conformity with the technical documentation referred to in Section 3 of Annex 7 and meet the
requirements of this Decree which apply to them.
7. Application to devices referred to in Article 2 (2 d)
Upon completing the manufacture of each batch of devices referred to in Article 2 (2 d), the
manufacturer shall inform the notified body of this batch of devices and send to it the official
certificate concerning the release of the batch of human blood derivative used in the device
issued by the laboratory in accordance with Annex 1, Point A, Section II. 7.4, third
subparagraph.

B. In case of active implants:
1. The manufacturer must ensure application of the quality system approved for the
manufacture of the products concerned and carry out the final inspection, as specified in

Section 3, and is subject to the surveillance referred to in Section 4.
2. The declaration of conformity is the part of the procedure whereby the manufacturer
who fulfils the obligations imposed by Section 1 ensures and declares that the products
concerned meet the provisions of this Decree which apply to them.
The manufacturer or the authorised representative must affix the CE marking in

accordance with Article 3 and draw up a written declaration of conformity. This declaration
must cover one or several number of identified specimens of the products manufactured and
must be kept by the manufacturer.
3. Quality system
3.1. The manufacturer must lodge an application for assessment of his quality system with
a notified body. The application must include:
a) all the relevant information on the product category covered by the procedure,
b) the documentation on the quality system,
c) an undertaking to fulfil the obligations imposed by the quality system approved,
d) an undertaking to maintain the practicability and effectiveness of the approved quality
system,
e) where appropriate, the technical documentation on the types approved and a copy of the
type-examination certificates,
f) an undertaking by the manufacturer to institute and keep up to date a systematic
procedure to review experience gained from devices in the post-production phase. This
undertaking must include an obligation for the manufacturer to notify on the incidents
immediately on learning of them, according to Article 14.
3.2. Application of the quality system must ensure that the products conform to the type
described in the type-examination certificate. All the elements, requirements and provisions
adopted by the manufacturer for his quality system must be documented in a systematic and
orderly manner in the form of written policy statements and procedures. This quality system
documentation must permit uniform interpretation of the quality policy and procedures such

as quality programmes, plans, manuals and records. It must include in particular an adequate
description of:
a) the manufacturer' s quality objectives;
b) the organization of the business and in particular:
- the organizational structures, the responsibilities of the managerial staff and their
organizational authority where manufacture of the products is concerned,
35 - the methods of monitoring the efficient operation of the quality system and in particular
its ability to achieve the desired quality of product, including control of products which fail to
conform;
c) the inspection and quality assurance techniques at the manufacturing stage and in
particular:
- the processes and procedures which will be used, particularly as regards sterilization,
purchasing and the relevant documents,
- the product identification procedures drawn up and kept up to date from drawings,
specifications or other relevant documents at every stage of manufacture;
d) the appropriate tests and trials to be carried out before, during and after manufacture, the
frequency with which they will take place, and the test equipment used.
3.3. The notified body must audit the quality system to determine whether it meets the
requirements referred to in Section 3.2. It must presume that quality systems which
implement the relevant harmonized standards conform to these requirements. The assessment
team must include at least one member with past experience of assessments of the technology
concerned. The assessment procedure must include an inspection on the manufacturer' s
premises, in duly substantiated cases, on the premises of the manufacturer' s suppliers to
inspect the manufacturing processes.
The decision must be notified to the manufacturer after the final inspection and contain the
conclusions of the inspection and a reasoned assessment.
3.4. The manufacturer must inform the notified body which approved the quality system of
any plan for substantial changes to the quality system or the range of

products. The notified
body must assess the changes proposed and verify whether after these changes the quality
system still meets the requirements referred to in Section 3.2. The decision must be notified to
the manufacturer. It must contain the conclusions of the inspection and a reasoned
assessment.
4. Surveillance
4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations
imposed by the approved quality system.
4.2. The manufacturer authorizes the notified body to carry out all the necessary
inspections and must supply it with all relevant information, in particular:
a) the documentation on the quality system,
b) the data stipulated in the part of the quality system relating to manufacture, such as
inspection reports and test data, calibration data, qualification reports of the personnel
concerned, etc.
4.3. The notified body must periodically carry out appropriate inspections and assessments
to make sure that the manufacturer applies the approved quality system and supply the
manufacturer with an assessment report.
4.4. The notified body may pay unannounced visits to the manufacturer. It must provide
the manufacturer with an inspection report.
5. The notified body must make available to the other notified bodies, on request, all
relevant information concerning the quality system approvals issued, refused or withdrawn.
ANNEX 6
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM

Product quality assurance
1. The manufacturer must ensure application of the quality system approved for the final
36 inspection and testing of the product, as specified in Section 3 and must be subject to the
surveillance referred to in Section 4. In addition, for products placed on the market in sterile
condition, and only for those aspects of the manufacturing process designed to secure and

maintain sterility, the manufacturer must apply the provisions of Annex 5, Parts A, Sections 3
and 4.
2. The declaration of conformity is the part of the procedure whereby the manufacturer
who fulfils the obligations imposed by Section 1 ensures and declares that the products
concerned conform to the type described in the type-examination certificate and meet the
provisions of this Decree which apply to them. The manufacturer affixes the CE marking in
accordance with Article 3 and draws up a written declaration of conformity. This declaration
must cover a given number of identified specimens of the products manufactured and be kept
by the manufacturer. The CE marking must be accompanied by the identification number of
the notified body which performs the tasks referred to in this Annex.
3. Quality system
3.1. The manufacturer lodges an application for assessment of his quality system with a
notified body.
The application must include:
a) the name and address of the manufacturer,
b) all the relevant information on the product or product category covered by the
procedure,
c) a written declaration specifying that no application has been lodged with any other
notified body for the same products,
d) the documentation on the quality system,
e) an undertaking by the manufacturer to fulfil the obligations imposed by the quality
system approved,
f) where appropriate, the technical documentation on the types approved and a copy of the
EC type-examination certificates,
g) an undertaking by the manufacturer to institute and keep up to date a systematic
procedure to review experience gained from devices in the post-production phase and to
implement appropriate means to apply any necessary corrective action. This undertaking must
include an obligation for the manufacturer to notify of the incidents

immediately on learning
of them according to Article 14.
3.2. Under the quality system, each product or a representative sample of each batch is
examined and the appropriate tests defined in the relevant standard(s) referred to in Article 2
or equivalent tests are carried out to ensure that the products conform to the type described in
the type-examination certificate and fulfil the provisions of this Decree which apply to them.
All the elements, requirements and provisions adopted by the manufacturer must be
documented in a systematic and orderly manner in the form of written measures, procedures
and instructions. This quality system documentation must permit uniform interpretation of the
quality programmes, quality plans, quality manuals and quality records. It must include in
particular an adequate description of:
a) the quality objectives and the organizational structure, responsibilities and powers of the
managerial staff with regard to product quality.
b) the examinations and tests that will be carried out after manufacture; it must be possible
to trace back the calibration of the test equipment adequately,
c) the methods of monitoring the efficient operation of the quality system,
d) the quality records, such as reports concerning inspections, tests, calibration and the
qualifications of the staff concerned, etc.
The aforementioned checks do not apply to those aspects of the manufacturing process
designed to secure sterility.
37 3.3. The notified body audits the quality system to determine whether it meets the
requirements referred to in Section 3.2. It must presume that quality systems which
implement the relevant harmonized standards conform to these requirements. The assessment
team must include at least one member with past experience of assessments of the technology
concerned. The assessment procedure must include an inspection on the manufacturer' s
premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers to
inspect the manufacturing processes. After the last inspection the decision

must be notified to
the manufacturer, it must contain the conclusions of the inspection and a reasoned assessment.
3.4. The manufacturer must inform the notified body which approved the quality system of
any plan for substantial changes to the quality system. The notified body must assess the
changes proposed and verify whether after these changes the quality system will still meet the
requirements referred to in Section 3.2. The decision must be notified to the manufacturer.
This decision must contain the conclusions of the inspection and a reasoned assessment.
4. Surveillance
4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations
imposed by the approved quality system.
4.2. The manufacturer must allow the notified body access for inspection purposes to the
inspection, testing and storage locations and supply it with all relevant information, in
particular:
a) the documentation on the quality system.
b) the technical documentation.
c) the quality records, such as inspection reports, test data, calibration data, qualification
reports of the staff concerned, etc.
4.3. The notified body must periodically carry out appropriate inspections and assessments
to make sure that the manufacturer applies the quality system and must supply the
manufacturer with an assessment report.
4.4. The notified body may pay unannounced visits to the manufacturer. At the time of
such visits, the notified body may, where necessary, carry out or ask for tests in order to
check that the quality system is working properly and that the production conforms to the
requirements of the Decree which apply to it. To this end, an adequate sample of the final
products taken on site by the notified body, must be examined and the appropriate tests
defined in the relevant standard(s) referred to in Article 2 or equivalent tests must be carried

out. Where one or more of the samples fails to conform, the notified body must take the
appropriate measures. It must provide the manufacturer with an inspection report and if a test
has been carried out, with a test report.
5. Administrative provisions
5.1. The manufacturer must, for a period ending at least five years after the last product has
been manufactured, make available to the Authority:
a) the declaration of conformity,
b) the documentation referred to Section 3.1.(g),
c) the changes referred to in Section 3.4,
d) the decisions and reports from the notified body as referred to in Section 4.3 and 4.4,
e) where appropriate, the type-examination certificate referred to in Annex 3.

6. Application to devices in Class IIa
In line with Article 6 (2), this Annex may apply to products in Class IIa, subject to this
derogation: by derogation from Sections 2, 3.1 and 3.2 by virtue of the declaration of
conformity the manufacturer ensures and declares that the products in Class IIa are
manufactured in conformity with the technical documentation referred to in Section 3 of
Annex 7 and meet the requirements of this Decree which apply to them.
38 ANNEX 7
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM
Declaration of conformity
1. The declaration of conformity is the procedure whereby the manufacturer or his
authorized representative who fulfils the obligations imposed by Section 2 and, in the case of
products placed on the market in a sterile condition and devices with a measuring function,
the obligations imposed by Section 5 ensures and declares that the products concerned meet
the provisions of this Decree which apply to them.
2. The manufacturer must prepare the technical documentation described in Section 3. The
manufacturer or his authorized representative must make this documentation, including the
declaration of conformity, available to the Authority for inspection purposes for a period
ending at least five years after the last product has been manufactured. Where

neither the
manufacturer nor his authorized representative are established in Hungary, this obligation to
keep the technical documentation available must fall to the person(s) who place(s) the product
on the market.
3. The technical documentation must allow assessment of the conformity of the product
with the requirements of the Decree. It must include in particular:
a) a general description of the product, including any variants planned,
b) design drawings, methods of manufacture envisaged and diagrams of components, subassemblies, circuits, etc.,
c) the descriptions and explanations necessary to understand the abovementioned drawings
and diagrams and the operations of the product,
d) the results of the risk analysis and a list of the standards referred to in Article 2, applied
in full or in part, and descriptions of the solutions adopted to meet the essential requirements
of the Decree if the standards referred to in Article 2 have not been applied in full,
e) in the case of products placed on the market in a sterile condition, description of the
methods used,
f) the results of the design calculations and of the inspections carried out, etc.,
g) if the device is to be connected to other devices in order to operate as intended, proof
must be provided that it conforms to the essential requirements when connected to any such
device(s) having the characteristics specified by the manufacturer,
h) the test reports and, where appropriate, data of clinical evaluation in accordance with
Annex 10,
i) the label and instructions for use.
4. The manufacturer shall institute and keep up to date a systematic procedure to review
experience gained from devices in the post-production phase and to implement appropriate
means to apply any necessary corrective actions. This undertaking must include an obligation
for the manufacturer to notify the competent authorities of the incidents immediately on
learning of them, according to Article 14.

5. In the case of Class I products placed on the marker in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex 4, 5 or 6. Application of the above mentioned Annexes and the intervention by the notified body is limited to:
a) in the case of products placed on the market in sterile condition, only the aspects of manufacture concerned with securing and maintaining sterile conditions.
b) in the case of devices with measuring function, only the aspects of manufacture concerned with the conformity of the products with the metrological requirements.
39 Section 6.1. of this Annex is applicable.
6. Application to devices in Class IIa
In line with Article 6 (2), this Annex may apply to products in Class IIa, subject to the following derogation:
6.1. Where this Annex is applied in conjunction with the procedure referred to in Annex 4, 5 or 6, the declaration of conformity referred to in the above mentioned Annexes forms a single declaration. As regards the declaration based on this Annex, the manufacturer must ensure and declare that the product design meets the provisions of this Decree which apply to it.
ANNEX 8
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM

A. Declaration concerning custom-made devices and classified devices intended for clinical investigations
1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative must draw up the statement containing the information stipulated in Section 2.
2. The statement must contain the following information:
2.1. For custom-made devices:
a) data allowing identification of the device in question,
b) a statement that the device is intended for exclusive use by a particular patient, together

with the name of the patient (certificate made out by the manufacturer),
c) the name of the medical practitioner or other authorized person who made out the
prescription and, where applicable, the name of the health care provider concerned,
d) the particular features of the device as specified in the relevant medical prescription,
e) a statement that the device in question conforms to the essential requirements set out in
Annex 1 and, where applicable, indicating which essential requirements have not been fully
met, together with the grounds.
2.2. For devices intended for the clinical investigations:
a) data allowing identification of the device in question,
b) an investigation plan stating in particular the purpose, scientific, technical or medical
grounds, scope and number of devices concerned,
c) the professional-ethical opinion according to paragraph (1) of Article 10 of the decree on
medical scientific researches or the professional-ethical authorization according to Article
20/D of the same decree,
d) the name of the medical practitioner or other authorized person and of the institution
responsible for the investigations,
e) the place, starting date and scheduled duration for the investigations,
f) a statement that the device in question conforms to the essential requirements apart from
the aspects covered by the investigations and that, with regard to these aspects, every
precaution has been taken to protect the health and safety of the patient.
3. The manufacturer must also undertake to keep available for the Authority:
3.1. For custom-made devices, documentation allowing an understanding of the design,
manufacture and performances of the product, including the expected performances, so as to
allow assessment of conformity with the requirements of this Decree.
The manufacturer must take all the measures necessary to ensure that the manufacturing
process produces products which are manufactured in accordance with the documentation
40 mentioned in the previous paragraph.
3.2. For devices intended for clinical investigations, the documentation must contain:

a) a general description of the product,
b) design drawings, methods of manufacture envisaged, in particular as regards sterilization, and diagrams of components, sub-assemblies, circuits, etc.,
c) the descriptions and explanations necessary to understand the abovementioned drawings and diagrams and the operation of the product,
d) the results of the risk analysis and a list of the standards referred to in Article 2 applied in full or in part, and descriptions of the solutions adopted to meet the essential requirements of this Decree if the standards referred to in Article 2 have not been applied.
e) the results of the design calculations, and of the inspections and technical tests carried out, etc.
The manufacturer must take all the measures necessary to ensure that the manufacturing process produces products which meet the documentation referred to in this Section. The manufacturer must authorize the assessment, or audit where necessary, of the effectiveness of these measures.
4. The information contained in the declarations concerned by this Annex should be kept for a period of time of at least five years.

B. Declaration concerning custom-made active implants and active implants intended for clinical investigations
1. For custom-made devices or for devices intended for clinical investigations the manufacturer or his authorized representative must draw up the statement containing the information stipulated in Section 2.
2. The statement must contain the following information:
2.1. For custom-made devices:
a) data allowing identification of the device in question,
b) a statement that the device is intended for exclusive use by a particular patient, together with the name of the patient (certificate made out by the manufacturer),
c) the name of the medical practitioner who made out the prescription and, where applicable, the name of the health care provider concerned,
d) the particular features of the device as specified in the relevant medical

prescription,
e) a statement that the device in question conforms to the essential requirements set out in
Annex 1 and, where applicable, indicating which essential requirements have not been fully
met, together with the grounds.
2.2. For devices intended for the clinical investigations:
a) data allowing identification of the device in question,
b) an investigation plan stating in particular the purpose, scientific, technical or medical
grounds, scope and number of devices concerned ,
c) the name of the medical practitioner and of the institution responsible for the
investigations
d) the place, starting date and scheduled duration for the investigations,
e) a statement that the device in question conforms to the essential requirements apart from
the aspects covered by the investigations and that, with regard to these aspects, every
precaution has been taken to protect the health and safety of the patient.
3. The manufacturer must also undertake to keep available for the Authority:
3.1. For custom-made devices, documentation allowing an understanding of the design,
manufacture and performances of the product, including the expected performances, so as to
41 allow assessment of conformity with the requirements of this Decree.
The manufacturer must take all the measures necessary to ensure that the manufacturing
process produces products which are manufactured in accordance with the documentation
mentioned in the previous paragraph.
3.2. For devices intended for clinical investigations, the documentation must contain:
a) a general description of the product,
b) design drawings, methods of manufacture envisaged, in particular as regards

sterilization, and diagrams of components, sub-assemblies, circuits, etc.,
c) the descriptions and explanations necessary to understand the above mentioned
drawings and diagrams and the operation of the product,
d) the list of the standards referred to in Article 2. applied in full or in part, and
descriptions of the solutions adopted to meet the essential requirements of this Decree if the
standards referred to in Article 2 have not been applied or applied in part.

e) the results of the design calculations, and of the inspections and technical tests carried
out, etc.
The manufacturer must take all the measures necessary to ensure that the manufacturing
process produces products which are manufactured in accordance with the documentation
referred to in Section 3.1 and the last indent of the previous Section.
The manufacturer may authorize the assessment, or audit where necessary, of the
effectiveness of these measures.
ANNEX 9
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM

Classification criteria

I. Definitions

1. Definitions for the classification rules
1.1. Duration
Transient: Normally intended for continuous use for less than 60 minutes.
Short term: Normally intended for continuous use for not more than 30 days.
Long term: Normally intended for continuous use for more than 30 days.
1.2. Invasive devices
Invasive device: A device which, in whole or in part, penetrates inside the body, either
through a body orifice or through the surface of the body.
Body orifice: Any natural opening in the body, as well as the external surface of the
eyeball, or any permanent surgical opening, such as a stoma.
Surgically invasive device: An invasive device which penetrates inside the body through
the surface of the body, with the aid or in the context of a surgical operation.
Implantable device: Any device which is intended:
- to be totally introduced into the human body or,
- to replace an epithelial surface or the surface of the eye,
by surgical intervention which is intended to remain in place after the procedure.
Any device intended to be partially introduced into the human body through surgical
intervention and intended to remain in place after the procedure for at least 30 days is also
considered an implantable device.

1.3. Reusable surgical instrument: Instrument intended for surgical use by cutting, drilling,
42 sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without
connection to any active medical device and which can be reused after appropriate procedures
have been carried out.
1.4. Active medical device: Any medical device operation of which depends on a source of
electrical energy or any source of power other than that directly originates from the human
body or gravity .
Medical devices intended to transmit energy, substances or other elements between an
active medical device and the patient, without any significant change are not considered to be
active medical devices.
1.5. Active therapeutical device: Any active medical device, whether used alone or in
combination with other medical devices, to support, modify, replace or restore biological
functions and structures with a view to treatment or alleviation of an illness, injury or
handicap.
1.6. Active device for diagnosis: Any active medical device, whether used alone or in
combination with other medical devices, to supply information for diagnosing, monitoring or
treating physiological conditions, illnesses or congenital deformities.
1.7. Central circulatory system: For the purposes of this Decree, ‘central circulatory
system’ means the following vessels: arteriae pulmonales, aorta ascendens, arteriae
coronariae, arteria carotis communis, arteria carotis externa, arteria carotis interna, arteriae
cerebrales, truncus brachicephahcus, venae cordis, venae pulmonales, vena cava superior,
vena cava inferior.
1.8. Central nervous system: For the purposes of this Decree, ‘central nervous system’
means brain, meninges and spinal cord.
II. Implementing rules

2. Implementing rules
2.1. Application of the classification rules shall be governed by the intended

purpose of the
devices.
2.2. If the device is intended to be used in combination with another device, the
classification rules shall apply separately to each of the devices.
Accessories are classified in
their own right separately from the device with which they are used.
2.3. Software, which drives a device or influences the use of a device, falls automatically
in the same class.
2.4. If the device is not intended to be used solely or principally in a specific part of the
body, it must be classified on the basis of the most critical specified use.
2.5. If several rules apply to the same device, based on the performance specified for the
device by the manufacturer, the strictest rules resulting in the higher classification rule shall
apply.
III. Classification

1. Non-invasive devices
1.1. Rule I
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.
1.2. Rule 2.
All non-invasive devices intended for channelling or storing blood, body liquids or tissues,
liquids or gases for the purpose of eventual infusion, administration or introduction into the
body are in Class IIa:
- if they may be connected to an active medical device in Class IIa or a higher class.
- if they are intended for use for storing or channelling blood or other body liquids or for
storing organs, parts of organs or body tissues.
43 in all other cases they are in Class I.
1.3. Rule 3
All non-invasive devices intended for modifying the biological or chemical composition of
blood, other body liquids or other liquids intended for infusion into the body are in Class IIb,
unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which
case they are in Class IIa.

1.4. Rule 4
All non-invasive devices which come into contact with injured skin:
- are in Class I if they are intended to be used as a mechanical barrier, for compression or
for absorption of exudates,
- are in Class IIb if they are intended to be used principally with wounds which have
breached the dermis and can only heal by secondary intent,
- are in Class IIa in all other cases, including devices principally intended to manage the
micro-environment of a wound.
2. Invasive devices
2.1. Rule 5
All invasive devices with respect to body orifices, other than surgically invasive devices
and which are not intended for connection to an active medical device:
- are in Class I if they are intended for transient use,
- are in Class IIa if they are intended for short-term use, except if they are used in the oral
cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which
case they are in Class I,
- are in Class IIb if they are intended for long-term use, except if they are used in the oral
cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not
liable to be absorbed by the mucous membrane, in which case they are in Class IIa.
All invasive devices with respect to body orifices, other than surgically invasive devices,
intended for connection to an active medical device in Class IIa or a higher class, are in Class
IIa.
2.2. Rule 6
All surgically invasive devices intended for transient use are in Class IIa unless they are:
- intended specifically to diagnose, monitor or correct a defect of the heart or of the central
circulatory system through direct contact with these parts of the body, in which case they are
in Class III,
- reusable surgical instruments, in which case they are in Class I,
- intended to supply energy in the form of ionizing radiation in which case they are in
Class IIb,

- intended to have a biological effect or to be wholly, or mainly absorbed in which case
they are in Class IIb,
- intended to administer medicines by means of a delivery system, if this is done in a
manner that is potentially hazardous taking account of the mode of application, in which they
are in Class IIb.

2.3. Rule 7

All surgically invasive devices intended for short-term use are in Class IIa unless they are
intended:
- either specifically to diagnose, monitor or correct a defect of the heart or of the central
circulatory system through direct contact with these parts of the body, in which case they are
in Class III,
- or specifically for use in direct contact with the central nervous system, in which case
they are in Class III,
- or to supply energy in the form of ionizing radiation in which case they are in Class IIb,
44 - or to have a biological effect or to be wholly or mainly absorbed in which case they are in
Class III,
- or to undergo chemical change in the body, except if the devices are placed in the teeth,
or to administer medicines, in which case they are in Class IIb.

2.4. Rule 8

All implantable devices and long-term surgically invasive devices are in Class IIb unless
they are intended:
- to be placed in the teeth, in which case they are in Class IIa,
- to be used in direct contact with the heart, the central circulatory system or the central
nervous system, in which case they are in Class III,
- to have a biological effect or to be wholly or mainly absorbed, in which case they are in
Class III,
- or to undergo chemical change in the body, except if the devices are placed in the teeth,
or to administer medicines, in which case they are in Class III.

3. Additional rules applicable to active devices

3.1. Rule 9

All active therapeutic devices intended to administer or exchange energy are in Class IIa
unless their characteristics are such that they may administer or exchange energy to or from
the human body in a potentially hazardous way, taking account of the nature, the density and
site of application of the energy, in which case they are in Class IIb.
All active devices intended to control or monitor the performance of active therapeutic
devices in Class IIb, or intended directly to influence the performance of such devices are in
Class IIb.
3.2. Rule 10
Active devices intended for diagnosis are in Class IIa:
- if they are intended to supply energy which will be absorbed by the human body, except
for devices used to illuminate the patient’ s body, in the visible spectrum,
- if they are intended to image in vivo distribution of radiopharmaceuticals,
- if they are intended to allow direct diagnosis or monitoring of vital physiological
processes, unless they are specifically intended for monitoring of vital physiological
parameters, where the nature of variations is such that it could result in immediate danger to
the patient, for instance variations in cardiac performance, respiration, activity of CNS in
which case they are in Class IIb.
Active devices intended to emit ionizing radiation and intended for diagnostic and
therapeutic interventional radiology including devices which control or monitor such devices,
or which directly influence their performance, are in Class IIb.
3.3. Rule 11
All active devices intended to administer and/or remove medicines, body liquids or other
substances to or from the body are in Class IIa, unless this is done in a manner: that is
potentially hazardous, taking account of the nature of the substances involved, of the part of
the body concerned and of the mode of application in which case they are in Class IIb.
3.4. Rule 12
All other active devices are in Class I.
4. Special Rules
4.1. Rule 13

All devices incorporating, as an integral part, a substance which, if used separately, can be
considered to be a medicinal product, and which is liable to act on the human body with
action ancillary to that of the devices, are in Class III. All devices incorporating, as an integral
part, a human blood derivative are in Class III.
4.2. Rule 14
45 All devices used for contraception or the prevention of the transmission of sexually
transmitted diseases are in Class IIb, unless they are implantable or long term invasive
devices, in which case they are in Class III.
4.3. Rule 15
All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when
appropriate, hydrating contact lenses are in Class IIb.
All devices intended specifically to be used for disinfecting medical devices are in Class
IIa.
This rule does not apply to products that are intended to clean medical devices other than
contact lenses by means of physical action.
4.4. Rule 16
Non-active devices specifically intended for recording of X-ray diagnostic images are in
Class IIa.
4.5. Rule 17
All devices manufactured utilizing animal tissues or derivatives rendered non-viable are
Class III except where such devices are intended to come into contact with intact skin only.
5. Rule 18
By derogation from other rules, blood bags are in Class IIb.
ANNEX 10
Decree of the Minister of Health No.

Clinical evaluation

A. In case of classified devices:
1. General provisions
1.1. In the case of devices in particular in the case of implantable devices and devices in
Class III the following procedures must be based on clinical data:

a) the confirmation of conformity with the requirements referred to in Sections I. 1 and 3
of Part A of Annex 1 under the normal conditions of use of the device;
b) the evaluation of the undesirable side-effects.
Taking account of any relevant harmonized standards, where appropriate, the adequacy of
the clinical data must be based on:
1.1.1. either a compilation of the relevant scientific literature currently available on the
intended purpose of the device and the techniques employed as well as, if appropriate, a
written report containing a critical evaluation of this compilation;
1.1.2. or the results of all the clinical investigations made, including those carried out in
conformity with Section 2.
1.2. The Authority must handle all the data in accordance with the provisions of data
protection regulations.
2. Clinical investigations
2.1. Objectives
The objectives of clinical investigation are:
a) to verify that, under normal conditions of use, the performance of the devices conform
to those referred to in Section I. 3 of Part A of Annex 1 and
b) to determine any undesirable side-effects under normal conditions of use, and assess
whether they constitute risks when weighed against the intended performance of the device.
2.2. Clinical investigations must be carried out in accordance with the principles laid down
in relevant legal regulation. This includes every step in the clinical investigation from first
consideration of the need to publication of the results.
46 2.3. Methods
2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of
investigation reflecting the latest scientific and technical knowledge and defined in such a
way as to confirm or refuse the manufacturer’ s claims for the device. These investigations
must include an adequate number of observations to guarantee the scientific validity of the
conclusions.
2.3.2. The procedures used to perform the investigations must be appropriate to the device

under examination.
2.3.3. Clinical investigations must be performed in circumstances similar to the normal
conditions of use of the device.
2.3.4. All the appropriate features, including those involving the safety and performances
of the device, and its effect on patients must be examined.
2.3.5. All adverse incidents such as those specified in Article 14 must be fully recorded and
notified to the Authority.
2.3.6. The investigations must be performed under the responsibility of a medical
practitioner or another authorized qualified person in an appropriate environment. The
medical practitioner or other authorized person must have access to the technical and clinical
data regarding the device.
2.3.7. The written report, signed by the medical practitioner or other authorized person
responsible, must contain a critical evaluation of all the data collected during the clinical
investigation.

B. In case of active implants:
1. General provisions
1.1. As a general rule, clinical data referred to in Section 4.2 (c) in Part B of Annex 2 and
Section 3 (g) in Part B of Annex 3, taking account of the relevant harmonized standards where
appropriate, must be based on:
1.1.1. either a compilation of the relevant scientific literature currently available on the
intended purpose of the device and the techniques employed as well as, if appropriate, a
written report containing a critical evaluation of this compilation;
1.1.2. or the results of all the clinical investigations made, including those carried out in
conformity with Section 2.
1.2. The Authority must handle all the dataconfidentially.
2. Clinical investigations
2.1. Objectives
The objectives of clinical investigation are:
a) to verify that, under normal conditions of use, the performance of the devices conform

to those referred to in Section 2 in Part B of Annex 1 and
b) to determine any undesirable side-effects under normal conditions of use, and assess
whether they constitute risks when weighed against the intended performance of the device.
2.2. Clinical investigations must be carried out in accordance with the principles laid down
in relevant legal regulation. This includes every step in the clinical investigation from first
consideration of the need to publication of the results.
2.3. Methods
2.3.1. Clinical investigations must be performed on the basis of an appropriate plan of
investigation reflecting the latest scientific and technical knowledge and defined in such a
way as to confirm or refuse the manufacturer’ s claims for the device. These investigations
must include an adequate number of observations to guarantee the scientific validity of the
conclusions.
2.3.2. The procedures used to perform the investigations must be appropriate to the device
47 under examination.
2.3.3. Clinical investigations must be performed in circumstances similar to the normal
conditions of use of the device.
2.3.4. All the appropriate features, including those involving the safety and performances
of the device, and its effect on patients must be examined.
2.3.5. All adverse incidents such as those specified in Article 14 must be fully recorded and
notified.
2.3.6. The investigations must be performed under the responsibility of a medical
practitioner in an appropriate environment.
The medical practitioner must have access to the technical and clinical data regarding the
device.
2.3.7. The written report, signed by the responsible medical practitioner must contain a
critical evaluation of all the data collected during the clinical investigation.

ANNEX 11
to Decree of the Minister of Health No.16/2006. (III. 27.) EüM

“CE” Marking of conformity
The CE conformity marking shall consist of the initials “CE” taking the following form:

If the marking is reduced or enlarged the proportions given in the above graduated drawing
must be respected.
The two letters of the CE marking must have substantially the same vertical dimension, which
may not be less than 5 mm.
This minimum dimension may be waived for small-scale devices.
ANNEX 12
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM
Form to the notification of unexpected events and to the notification for systematic recalls by
the manufacturer in connection with the devices of the decree on medical devices
Data of the Reporter:
Name of the Raporter
☐ Manufacturer
☐ Authorised representative
☐ Distributor
48 ☐ Importer
☐ Person responsible for marketing
☐ User
☐ Other
Street, house no. or PO Box
Postal code Town
Contact person
Telephone Fax
E-mail
Date of the notification
Data of the Medical Device:
Trade name
GMDN code
Name according to GMDN
Class
Type or catalogue no.
Serial number and/or LOT number
Accessories
Software version (when applicable)
Data of the Manufacturer:
Name

Street, house no.
Postal code Town
Country
Telephone Fax
E-mail
Data of the Authorised Representative
Other representatives in Hungary (distributor, service, etc.)
Event Data:
Date of the event
Place of the event
Description of the event
Outcome (e.g. death, deterioration in the state of health, event which might have led to
an incident)
Measures taken in connection with the event
Reason of the systematic recall
Maintenance Data:
Service construction (service contract: own service, servicing company, other)

Name and address of the servicing company
Date and data of the last periodical inspection (according to Article 17. and Annex 13 of
decree No.16/2006. (III. 27.) EüM)

Date of the last service intervention logged
49 Date of the last overhaul logged
Remark:
This report does not mean that the manufacturer, his authorised representative or the
competent authority confirms or acknowledges that the notified medical device might have
contributed in any way to the death of the patient concerned or the deterioration in his state of
health, or that the device might have caused the incident directly.
I affirm that the information given above is correct to the best of my knowledge.

Place: …….. Date: ……

…….
Signature

(The report shall be submitted to the Authority in one copy without delay, within at least 3
days.)

ANNEX 13
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM
Periodical inspection

I. Scope of equipment obliged to undergo periodical inspection, frequency of inspection
1. Defibrillator annually
2. High frequency surgical cutting instrument annually
3. Incubator annually
4. Anaesthesia ventilator annually
5. Operating lamp annually
6. Dialyse equipment annually
7. Invasive and interventional X ray equipment annually
50 8. Operating table biennially
9. Tonometer biennially
10. Traditional X ray examination and radiography work station biennially
11. Surgical imageintensifier biennially
12. Surgical and intensive care monitor, ECG biennially
13. Laser biennially
14. Invasive blood pressure meter and blood flow meter biennially
15. Mechanical infusior once in 3 years
16. Blood warming equipment once in 3 years
17. Sterilizing equipment once in 3 years
18. Mains operated electro therapeutic equipment
(stimulator, high frequency equipment, etc.) once in 3 years
19. Medical gas supply system once in 3 years
20. Ultrasound diagnostic equipment once in 3 years
II. Other provisions

1. The result of the inspection shall be recorded. The documentation shall be kept by the
person in the institute responsible for the instruments and at request shall present it to the
responsible person for labour safety, the supervising organization, the competent institute of
the State Public Health and Medical Officer Service (llami Népegészségügyi és Tisztiorvosi
Szolgálat) and the Authority. In addition to the result of the inspection its method of control
shall be indicated as well.
2. In case of instruments difficult to transport or that can be transported only at high costs
or in case of instruments even temporarily indispensable at the institution local inspection

method shall be ensured.
3. Periodical inspection shall be evaluated even after the service intervention following a
failure if the intervention also comprised the characteristic to be inspected.

4. The periodical inspection does not concern the mandatory tests (e.g. calibration) referred
to the scope of authority of other validating institution.
5. The first periodical inspection shall fall due after 1, 2 or 3 years depending on the
prescribed frequency, following the installation. The date of the following inspection shall be
counted from that of the previous one.
ANNEX 14
to Decree of the Minister of Health No. 16/2006. (III. 27.) EüM
51 REGISTRATION FORM
to the National Institute of Chemical Safety of Fodor József National Centre for Public Health
for placing medical devices of class II.a, those are intended expressly for disinfection of
medical devices, on the Hungarian market
Data of the Manufacturer, the Distributor or the Authorised Representative
Notifier (firm)
Name:
.....
Registered place of business:
.....
Address of the premises:.....
County: .....
Phone: ..... Telefax:
..... E-mail:
.....
Name of the contact person:
.....
Address of the contact person:
.....
Phone: ..... Telefax:
..... E-mail:
.....
Data of the marketed medical device (disinfectant)*
Name of the product
Name of the biocidal
active substance(s) **
Package unit Content of the
biocidal active

substance

Year of marketing:
Notes:
Signature, stamp, date:
* In case of more products (active substances) notification shall be continued on a new data sheet as necessary.
**Name of the active substance shall be indicated according to the special rule on list of dangerous substances
classified in the European Union, or if the name cannot be found here, then according to the European Inventory
of Existing Commercial Chemical Substances (EINECS). If there is no substance of name in question in the
aforementioned lists, then generally used name of the substance shall be given according to the International
Organization for Standardization (ISO). If there is no such name then it shall be indicated with the chemical
name according to the rules of International Union of Pure and Applied Chemistry (IUPAC).
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