manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) [.../...], the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements of Annex I of that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question, unless the authority is advised by its experts for medical devices that involvement of a notified body is not required.'

Article 92
Amendments to Regulation (EC) No 178/2002

In the third subparagraph of Article 2 of Regulation (EC) No 178/2002, the following point (i) is added:

'(i) medical devices within the meaning of Regulation (EU) [.../...][56].'

Article 93
Amendments to Regulation (EC) No 1223/2009

In Article 2 of Regulation (EC) No 1223/2009, the following paragraph is added:

'4. In accordance with the regulatory procedure referred to in Article 32(2), the Commission may, at the request of a Member State or on its own initiative, adopt the necessary measures to determine whether or not a specific product or group of products falls within the definition 'cosmetic product'.'

Article 94
Transitional provisions

1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directives 90/385/EEC and 93/42/EEC shall become void.

2. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 of Directive 90/385/EEC or Annex IV of Directive 93/42/EEC which shall become void at the latest two years after the date of application of this Regulation.

   Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.

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56 OJ L [...], [...], p. [...].

3. By way of derogation from Directives 90/385/EEC and 93/42/EEC, devices which comply with this Regulation may be placed on the market before its date of application.

4. By way of derogation from Directives 90/385/EEC and 93/42/EEC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.

5. By way of derogation from Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 25(2) and (3) and Article 45(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with, respectively, Article 10a of Directive 90/385/EEC or Article 14(1) and (2) of Directive 93/42/EEC and with, respectively, point (a) of Article 10b(1) of Directive 90/385/EEC or points (a) and (b) of Article 14a(1) of Directive 93/42/EEC as specified in Commission Decision 2010/227/EU.

6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(9) of Directive 90/385/EEC or Article 11(13) of Directive 93/42/EEC shall keep the validity indicated in the authorisation.

7. Devices falling within the scope of this Regulation in accordance with point (e) of Article 1(2) which have been legally placed on the market or put into service in accordance with the rules in force in the Member States prior to the application of this Regulation may continue to be placed on the market and put into service in the Member States concerned.

8. Clinical investigations which have started to be conducted in accordance with Article 10 of Directive 90/385/EEC or Article 15 of Directive 93/42/EEC prior to the application of this Regulation may continue to be conducted. As of the application of this Regulation, however, the reporting of serious adverse events and device deficiencies shall be carried out in accordance with this Regulation.

Article 95
Evaluation

No later than seven years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation.

Article 96
Repeal

Council Directives 90/385/EEC and 93/42/EEC are repealed with effect from [date of application of this Regulation], with the exception of Article 10a and point (a) of Article 10b(1) of Directive 90/385/EEC and Article 14(1) and (2) and points (a) and (b) of Article 14a(1) of Directive 93/42/EEC which are repealed with effect from [18 months after date of application].

References to the repealed Council Directives shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid down in Annex XVI.

Article 97
Entry into force and date of application

1. This Regulation shall enter into force on the twentieth day after its publication in the *Official Journal of the European Union.*

2. It shall apply from [three years after entry into force].

3. By way of derogation from paragraph 2 the following shall apply:

   (a) Article 25(2) and (3) and Article 45(4) shall apply from [18 months after date of application referred to in paragraph 2];

   (b) Articles 28 to 40 and Article 78 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 28 to 40 shall apply only to those bodies which submit an application for notification in accordance with Article 31 of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

I. General requirements

1. Devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art. They shall 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.

   This shall include:

   – reducing as far as possible the risk of use error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and

   – consideration of the technical knowledge, experience, education and training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

2. The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:

   (a) identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse;

   (b) eliminate risks as far as possible through inherently safe design and manufacture;

   (c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and

   (d) provide training to users and/or inform users of any residual risks.

3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user 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 and has been properly maintained in accordance with the manufacturer's instructions. When no lifetime is stated, the same applies for the lifetime reasonably to be expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.

4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.

5. All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the benefits to the patient of the achieved performance of the device during normal conditions of use.

6. For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, the general requirements set out in Sections 1 and 5 shall be understood that the device, when used under the conditions and for the purposes intended, shall not present any risk or only the minimum acceptable risks related to the product's use which is consistent with a high level of protection for the safety and health of persons.

II. Requirements regarding design and construction

7. Chemical, physical and biological properties

7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall 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;

(c) where appropriate, the results of biophysical or modelling research whose validity has been demonstrated beforehand;

(d) the choice of materials used, reflecting, where appropriate, matters such as hardness, wear and fatigue strength.

7.2. The devices shall be designed, manufactured and packaged in such a way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.

7.3. The devices shall be designed and manufactured in such a way that they can be used safely with the materials and substances, including 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 shall 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 medicinal products and that both the performance of the medicinal products and of the devices are maintained in accordance with their respective indications and intended use.

7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks posed by substances that may leach or leak from the device. Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006[57], and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[58].

If devices, or parts thereof, that are intended

- to be invasive devices and to come into contact with the body of the patient for short- or long-term, or
- to (re)administer medicines, body liquids or other substances, including gases, to/from the body, or
- to transport or store such medicines, body fluids or substances, including gases, to be (re)administered to the body

contain, in a concentration of 0.1% by mass of the plasticised material or above, phthalates which are classified as carcinogenic, mutagenic or toxic to reproduction of category 1A or 1B in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008, these devices shall be labelled on the device itself and/or on the packaging for each unit or, where appropriate, on the sales packaging as devices containing phthalates. If the intended use of such devices includes treatment of children or treatment of pregnant or nursing women, the manufacturer shall provide a specific justification for the use of these substances with regard to compliance with the general safety and performance requirements, in particular of this paragraph, within the technical documentation and, within the instructions for use, information on residual risks for these patient groups and, if applicable, on appropriate precautionary measures.

7.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate risks posed by the unintentional ingress or egress of substances into or from the device taking into account the device and the nature of the environment in which it is intended to be used.

7.6. The devices shall be designed and manufactured in such a way as to reduce to a minimum the risks linked to the size and the properties of particles used. Special care shall be applied when devices contain or consist of nanomaterial that can be released into the patient's or user's body.

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57 OJ L 353, 31.12.2008, p. 1.
58 OJ L 136, 29.5.2007, p.3.

8. Infection and microbial contamination

8.1. The devices and manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall:

(a) allow easy handling,

and, where necessary,

(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use,

(c) prevent microbial contamination of the device or specimen.

8.2. Devices labelled as having a special microbiological state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market and remain so under the transport and storage conditions specified by the manufacturer.

8.3. Devices delivered in a sterile state shall be designed, manufactured and packaged 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 transport and storage conditions indicated by the manufacturer, until the protective packaging is damaged or opened.

8.4. Devices labelled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilised by appropriate, validated methods.

8.5. Devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.

8.6. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

8.7. The labelling of the device shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

9. Devices incorporating a substance considered to be a medicinal product and devices composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally

9.1. In the case of devices referred to in the first subparagraph of Article 1(4), the quality, safety and usefulness of the substance which, if used separately, would be considered to be a medicinal product within the meaning of Article 1 of Directive 2001/83/EC, shall be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC, as laid down in the applicable conformity assessment procedure in this Regulation.

9.2. Devices that are composed of substances or combination of substances intended to be ingested, inhaled or administered rectally or vaginally and that are absorbed by or dispersed in the human body shall comply, by analogy, with the relevant requirements laid down in Annex I to Directive 2001/83/EC.

10. Devices incorporating materials of biological origin

10.1. For devices manufactured utilising tissues or cells, or their derivatives, of human origin which are covered by this Regulation in accordance with point (e) of Article 1(2) the following applies:

(a) Donation, procurement and testing of tissues and cells of human origin used for the manufacture of devices shall be made in accordance with Directive 2004/23/EC.

(b) The processing, preservation and any other handling of those tissues and cells shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

(c) It shall be ensured that the traceability system for devices manufactured utilising those human tissues or cells is complementary and compatible with the traceability and data protection requirements laid down in Directive 2004/23/EC and in Directive 2002/98/EC of the European Parliament and of the Council of 27 January 2003 setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC[59].

10.2. For devices manufactured utilising tissues or cells, or their derivatives, of animal origin which are non-viable or rendered non-viable the following applies:

(a) Where feasible taking into account the animal species, tissues and cells of animal origin shall originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. Information on the geographical origin of the animals shall be retained.

(b) Processing, preservation, testing and handling of tissues, cells and substances of animal origin shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.

(c) In the case of devices manufactured utilising tissues or cells of animal origin as referred to in Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active

[59] OJ L 33, 8.2.2003, p. 30.

implantable medical devices and medical devices manufactured utilising tissues of animal origin[60], the particular requirements laid down in that Regulation shall apply.

10.3. For devices manufactured utilising other non-viable biological substances the following applies:

In the case of biological substances other than those referred to in Sections 10.1. and 10.2., the processing, preservation, testing and handling of those substances shall be carried out so as to provide optimal safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process.

11. Interaction of devices with their environment

11.1. If the device is intended for use in combination with other devices or equipment the whole combination, including the connection system shall be safe and shall not impair the specified performance of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle, such as fluid, gas transfer or mechanical coupling, shall be designed and constructed in such a way as to minimize all possible risks from incorrect connection.

11.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:

(a) the risk of injury to the patient, user or other persons in connection with their physical and ergonomic features;

(b) the risk of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;

(c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;

(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;

(e) the risk associated with the possible negative interaction between software and the environment within which it operates and interacts;

(f) the risks of accidental ingress of substances into the device;

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60 OJ L 212, 9.8.2012, p. 3.

(g) the risks of reciprocal interference with other devices normally used in the investigations or for the treatment given;

(h) 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.

11.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition. Particular attention shall be paid to devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.

11.4. Devices shall be designed and manufactured in such a way that adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.

11.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such as way that the interoperability is reliable and safe.

11.6. Any measurement, monitoring or display scale shall be designed in line with ergonomic principles, taking account of the intended purpose of the device.

11.7. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, patient or other person.

12. Devices with a diagnostic or measuring function

12.1. Diagnostic devices and devices with a measuring function, shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose, based on appropriate scientific and technical methods. The limits of accuracy shall be indicated by the manufacturer.

12.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC[61].

13. Protection against radiation

13.1. General

(a) Devices shall be designed and manufactured and packaged in such a way that exposure of patients, users and other persons to any emitted radiation shall be reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.

(b) The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the

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61 OJ L 39, 15.2.1980.

patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in installation.

13.2. Intended radiation

(a) Where devices are designed to emit hazardous, or potentially hazardous, levels of visible and/or invisible radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, it shall be possible for the user to control the emissions. Such devices shall be designed and manufactured to ensure reproducibility of relevant variable parameters within an acceptable tolerance.

(b) Where devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall be fitted, where possible, with visual displays and/or audible warnings of such emissions.

13.3. Unintended radiation

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 and appropriate.

13.4. Ionising radiation

(a) Devices intended to emit ionising radiation shall be designed and manufactured in such a way as to ensure that, where possible, the quantity, geometry and energy distribution (or quality) of radiation emitted can be varied and controlled taking into account the intended use.

(b) Devices emitting ionising radiation intended for diagnostic radiology shall be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimising radiation exposure of the patient and user.

(c) Devices emitting ionising 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 characteristics in terms of type of radiations, energy and, where appropriate, energy distribution.

14. Software incorporated in devices and standalone software

14.1. Devices that incorporate electronic programmable systems, including software, or standalone software that are devices in themselves, shall be designed to ensure repeatability, reliability and performance according to the intended use. In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

14.2. For devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, verification and validation.

14.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).

15. Active devices and devices connected to them

15.1. For active devices, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.

15.2. Devices where the safety of the patients depends on an internal power supply shall be equipped with a means of determining the state of the power supply.

15.3. Devices where the safety of the patients depends on an external power supply shall include an alarm system to signal any power failure.

15.4. Devices intended to monitor one or more clinical parameters of a patient shall 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.

15.5. Devices shall be designed and manufactured in such a way as to reduce as far as possible and appropriate the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.

15.6. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

15.7. Devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.

16. Protection against mechanical and thermal risks

16.1. Devices shall be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance to movement, instability and moving parts.

16.2. Devices shall 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.

16.3. Devices shall 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.

16.4. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user or other person has to handle shall be designed and constructed in such a way as to minimise all possible risks.

16.5. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings.

The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.

16.6. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.

17. Protection against the risks posed to the patient or user by supplied energy or substances

17.1. Devices for supplying the patient with energy or substances shall be designed and constructed in such a way that the delivered amount can be set and maintained accurately enough to assure the safety of the patient and of the user.

17.2. Devices shall be fitted with the means of preventing and/or indicating any inadequacies in the delivered amount which could pose a danger. Devices shall incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

17.3. The function of the controls and indicators shall 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 shall be understandable to the user and, as appropriate, the patient.

18. Protection against the risks posed by medical devices intended by the manufacturer for use by lay persons

18.1. Devices for use by lay persons shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in the lay person's technique and environment. The information and instructions provided by the manufacturer shall be easy for the lay person to understand and apply.

18.2. Devices for use by lay persons shall be designed and manufactured in such a way as to

– ensure that the device is easy to use by the intended user at all stages of the procedure, and

– reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, in the interpretation of the results.

18.3. Devices for use by lay persons shall, where reasonably possible, include a procedure by which the lay person

– can verify that, at the time of use, the device will perform as intended by the manufacturer, and

– if applicable, is warned if the device has failed to provide a valid result.

III. Requirements regarding the information supplied with the device

19. Label and instructions for use

19.1. General requirements regarding the information supplied by the manufacturer

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate. Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:

(a) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.

(b) The information required on the label shall be provided on the device itself. If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.

Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.

(c) For devices of class I and IIa, instructions for use are not needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.

(d) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.

(e) Instructions for use may be provided to the user in non-paper format (e.g. electronic) to the extent and under the conditions set out in Commission Regulation (EU) No 207/2012 on electronic instructions for use of medical devices[62].

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[62] OJ L 72, 10.3.2012, p. 28.

(f) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.

(g) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.

19.2. Information on the label

The label shall bear the following particulars:

(a) The name or trade name of the device.

(b) The details strictly necessary for a user to identify the device, the contents of the packaging and, where it is not obvious for the user, the intended purpose of the device.

(c) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established.

(d) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted and his location be established.

(e) Where applicable, an indication that the device contains or incorporates

- a medicinal substance, including a human blood or plasma derivative, or
- tissues or cells, or their derivatives, of human origin, or
- tissues or cells, or their derivatives, of animal origin as referred to in Commission Regulation (EU) No 722/2012.

(f) Where applicable, an indication that the device incorporates or consists of nanomaterial unless the nanomaterial is encapsulated or bound in such a manner that it cannot be released into the patient's or user's body when the device is used within its intended purpose.

(g) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate.

(h) Where applicable, the unique device identification (UDI).

(i) An unambiguous indication of the date until when the device may be used safely, expressed at least as the year and month, where this is relevant.

(j) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable.

(k) An indication of any special storage and/or handling condition that applies.

(l) If the device is supplied sterile, an indication of its sterile state and the sterilisation method.

(m) Warnings or precautions to be taken that need to be brought to the immediate attention of the user of the device as relevant, and to any other person where appropriate. This information may be kept to a minimum in which case more detailed information should appear in the instructions for use.

(n) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union.

(o) If the device is a single use device that has been reprocessed, an indication of that fact, the number of reprocessing cycles already performed, and any limitation as regards the number of reprocessing cycles.

(p) If the device is custom made, an indication of that fact.

(q) If the device is intended for clinical investigation only, an indication of that fact.

19.3. Information in the instructions for use

The instructions for use shall contain the following particulars:

(a) The particulars referred to in points 19.2. a), c), e), f), k), l) and n).

(b) The device's intended purpose including the intended user (e.g. professional or lay person), as appropriate.

(c) The performance of the device intended by the manufacturer.

(d) Any residual risks, contraindications and any expected and foreseeable undesirable side-effects, including information to be conveyed to the patient in this regard.

(e) Specifications the user requires to use the device appropriately, e.g. if the device has a measuring function, the degree of accuracy claimed for it.

(f) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.).

(g) Any requirements for special facilities, or special training, or particular qualifications of the device user and/or other persons.

(h) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:

- details of the nature, and frequency, of preventative and regular maintenance, and of any preparatory cleaning or disinfection;
- identification of any consumable components and how to replace them;
- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;
- methods of eliminating the risks encountered by persons involved in installing, calibrating or servicing devices.

(i) If the device is supplied sterile, instructions in the event of the sterile packaging being damaged before use.

(j) If the device is supplied non-sterile with the intention that it is sterilised before use, the appropriate instructions for sterilisation.

(k) If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilisation. Information should be provided to identify when the device should no longer be reused, e.g. signs of material degradation or the maximum number of allowable reuses.

(l) If the device bears an indication that the device is for single use, information on known characteristics and technical factors known to the manufacturer that could pose a risk if the device were to be re-used. If in accordance with point c) of Section 19.1 no instructions for use are needed, the information shall be made available to the user upon request.

(m) For devices intended for use together with other devices and/or general purpose equipment:

- information to identify such devices or equipment, in order to obtain a safe combination, and/or
- information on any known restrictions to combinations of devices and equipment.

(n) If the device emits hazardous, or potentially hazardous levels of radiation for medical purposes:

- detailed information as to the nature, type and where appropriate, the intensity and distribution of the emitted radiation;
- the means of protecting the patient, user, or other person from unintended radiation during use of the device.

(o) Information that allows the user and/or patient to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information should cover, where appropriate:

- warnings, precautions and/or measures to be taken in the event of malfunction of the device or changes in its performance that may affect safety;

- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;

- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, or therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);

- if the device is intended to administer medicinal products, tissues or cells, or their derivatives, of human or animal origin or biological substances, any limitations or incompatibility in the choice of substances to be delivered;

- warnings, precautions and/or limitations related to the medicinal substance or biological material that is incorporated into the device as an integral part of the device;

- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user.

(p) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories and the consumables used with it, if any. This information should cover, where appropriate:

- infection or microbial hazards (e.g. explants, needles or surgical equipment contaminated with potentially infectious substances of human origin);

- physical hazards (e.g. from sharps).

(q) For devices intended for use by lay persons, the circumstances when the user should consult with a healthcare professional.

(r) For devices listed in Annex XV for which the manufacturer does not claim a medical purpose, information regarding the absence of a clinical benefit and the risks related to the use of the device.

(s) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use.

(t) A notice to the user and/or patient that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established.

ANNEX II

TECHNICAL DOCUMENTATION

The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by the manufacturer shall include in particular the following elements:

1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

(a) product or trade name and a general description of the device including its intended purpose,

(b) the UDI device identifier as referred to in item (i) of point (a) of Article 24(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;

(c) the intended patient population and medical condition to be diagnosed and/or treated and other considerations such as patient selection criteria;

(d) principles of operation of the device;

(e) risk class and the applicable classification rule according to Annex VII;

(f) an explanation of any novel features;

(g) a description of the accessories, other medical devices and other products that are not medical devices, which are intended to be used in combination with it;

(h) a description or complete list of the various configurations/variants of the device that will be made available;

(i) a general description of the key functional elements, e.g. its parts/components (including software if appropriate), its formulation, its composition, its functionality. Where appropriate, this shall include labelled pictorial representations (e.g. diagrams, photographs, and drawings), clearly indicating key parts/components, including sufficient explanation to understand the drawings and diagrams;

(j) a description of the (raw) materials incorporated into key functional elements and those making either direct contact with the human body or indirect contact with the body, e.g., during extracorporeal circulation of body fluids;

(k) technical specifications (features, dimensions and performance attributes) of the medical device and any variants and accessories that would typically