Manual for ITC's Clients 2016


Institute for Testing and Certification, Inc., Czech Republic
1. Introduction

The present Manual aims to inform customers of the Institute for Testing and Certification, joint-stock company, (hereinafter referred to as “ITC”) about their rights and obligations associated with cooperation in the conformity assessment procedure of medical devices (hereinafter referred to as “MD”) with Notified Body No. 1023.

Based on the decision of UNMZ (Czech Office for Standards, Metrology and Testing), ITC is authorized as Notified Body No. 1023 to perform activities in conformity assessment of all medical devices placed on the market of Member States of the European Union and European Free Trade Association (EFTA).

Technical requirements for medical devices as well as requirements on persons placing the medical devices on the market are governed by Council Directive 93/42/EEC, as amended (hereinafter referred to as “MDD”). This European legislation is implemented into the Czech legislation in the form of Government Decree No. 54/2015 Coll., on technical requirements for medical devices (hereinafter referred to as “GD 54”).

Practically, this means that by meeting the requirements laid down by GD 54, also requirements of the above Directive are met and the product, which has undergone conformity assessment by Notified Body No. 1023 based on these requirements may be placed on the market of all EU and EFTA Member States without any further restrictions and measures to be taken.

2. Enquiry

- The manufacturer of medical devices or manufacturer's authorized representative (hereinafter referred to as the “Client”) shall submit the completed questionnaire (“Preliminary Questionnaire for Potential Clients”) to Notified Body No. 1023.
- The questionnaire form is available for download on the ITC website: http://www.itczlin.cz/cz/zdravotnické-prostředky-ce
- The Client shall send the completed questionnaire either personally, by post, by fax or by e-mail to one of the contacts below:

Institut pro testování a certifikaci, a.s.
Department of Certification of Medical Devices

a) Jana Balusková (certification of medical devices)
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   phone (+420) 577 601 269, fax. (+420) 577 104 855, e-mail: jbaluskova@itczlin.cz

b) Markéta Klinkovská (certification of medical devices)
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   phone (+420) 577 601 266, fax. (+420) 577 104 855, e-mail: mklinkovska@itczlin.cz

c) Lýdia Remeteiová, (ITC Branch Office in Bratislava, certification of medical devices)
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   phone +421 253 421 046; fax. +421 253 421 032; e-mail: lremeteiova@itczlin.cz
Contacts to experts:

Ing. Tomáš Závišek (Head of department medical devices certification)
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Ing. Ľubica Škrovanová (Head of the ITC Branch Office in Bratislava, certification of medical devices)
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- Along with the questionnaire, it is necessary to submit the documentation specified in the questionnaire (such as advertising brochures for the products, instructions for use, copies of certificates already issued for the Client’s company where appropriate).
- The languages permissible for the questionnaire and the documentation are Czech, Slovak and/or English.
- In case of doubt, completion of the questionnaire may be consulted with an expert at the contact address listed above.
- The questionnaire is reviewed at ITC in terms of its completeness and relevance of present data.
- If the submitted questionnaire is incomplete, ITC shall specify the missing data in writing (via e-mail, letter or fax) and request completion of the details.
- After receiving the duly completed questionnaire supplemented with the required documentation, the responsible expert shall prepare the cost estimation for the required conformity assessment procedure.
- The resulting price quotation together with the anticipated date of commencement of works shall be sent to the Client.

3 Formal application

- If the potential Client agrees with the quoted price and the proposed starting date of conformity assessment, the Client shall submit the formal application for conformity assessment of medical devices, complemented by the technical documentation specified in Section 6.
- Upon delivery of the duly completed application and full technical documentation to the address of Notified Body No. 1023, the Client becomes the applicant and his application becomes a regular order. Together with the application, Notified Body No. 1023 shall receive the “General Framework Agreement” (hereinafter referred to as GFA) signed by the applicant, unless already submitted previously.
- The application form and GFA are available on the ITC website http://www.itczlin.cz/cz/zdravotnicke-prostredky-ce
- The application and the required documentation shall be submitted either in Czech, Slovak and/or English.
- In case of doubt, completion of the application may be consulted with an expert at the contact address listed above.
- The EU legislation does not allow the manufacturer or manufacturer’s authorised representative to file an application for service of an authorized or notified body for the same product with other entities.

4 Application review

- Upon its examination in terms of accuracy and completeness of data, the application is registered.
If the content or scope of the submitted application is incomplete, ITC shall specify in writing (by letter, e-mail, fax) the missing items and shall request their supplementation.

After receiving the fully completed application, it is registered in the ITC internal database and the Client is sent the information about the registration code assigned to such order. The applicant then receives relevant administrative documents (registration letter, draft contract and prepayment invoice).

The procedure of conformity assessment begins on the date when the Client fulfils the requirements of the duly concluded contract and settles the prepayment invoice.

5 Determination of price and delivery date

The contractual prices and delivery dates under the previous paragraph are usually calculated after receiving all the information necessary for determination of the scope of expert works, in particular the technical documentation.

The delivery date is given for the ideal case of conformity assessment, it may be extended based on the identified deficiencies.

6 Technical documentation

Basic identification data of the manufacturer (name, address, business registration number) or manufacturer's authorized representative, if relevant;

Information whether the manufacturer complies with the requirements for the quality management system pursuant to Czech technical standards ISO 9001 / EN ISO 9001, ISO 13485 / EN ISO 13485, or for another quality management system (such as "GMP");

Documentation from certification and supervisory audits, list of identified non-conformities if the manufacturer's quality management system is certified;

Description and specification of MD (trade name, models/types/variants, brief description of MD, intended purpose of MD, description of previous MD versions or reference to similar MD, declared function and/or benefits for a patient, statement regarding the content of integrated substances - medicinal products, animal tissue and its derivatives, human blood derivatives);

Classification of MD (classification rule used, justification for the use of the relevant classification rule and risk class to which the product belongs according to the manufacturer);

Nomenclature code according to GMDN (Global Medical Device Nomenclature);

Documentation describing MD manufacture (specification of the manufacturing place, specification of subcontractors of important technological processes or services, list of suppliers of input materials, description of the technological procedure including the control mechanisms, methods of sampling and product testing, methods of intake acceptance of materials, description of tests used for output control when releasing the product, distribution batch...);

Design drawings, schemes of components, subassemblies or circuits, including descriptions and explanations necessary to understand the drawings, schemes and functions of MD;

Risk analysis and risk management scheme (i.e. also the risk management plan and other system documents);

List of basic requirements of MDD and GD 54 with details of their application for the relevant medical device and way of their fulfillment;

List of standards and regulations used;

Documentation for design and construction of MD (drawings and illustrations of the product, specifications of parts and input materials of the product, measuring functions and metrological
sequence, radiation and electrical safety, electromagnetic compatibility, stability study, specification of the software used and its validation...);

- If the assessed MD is to be connected with other MD, it shall be proved that the MD complies with the essential requirements when being connected with the other MD;
- Documentation describing the method of sterilisation and its validation;
- Document confirming suitability of the packaging material used for the given sterilisation method;
- Manufacturer's information (instructions for use, information brochures, labels, labelling and information on the packaging of MD...) in Czech, Slovak or English language, and procedure for creating language mutations of the Manual and labelling by country of MD destination;
- Selected tests and determination of their frequency, applied standards, equipment used during the testing and methods of calibration, test results, stability studies or durability of medical devices;
- Preclinical study (specification of materials coming into contact with the patient and user, results of biocompatibility studies in accordance with the standards of EN ISO 10993 series, description and characterisation of nanoparticles used in the product, results of animal studies and results of tests of simulated use);
- Reports on clinical trials of MD. The scope of a clinical trial report is set out in Act No. 268/2014 Coll., Chapter III;
- Draft Declaration of Conformity;
- Copy of a contract with the authorised representative, if applicable;
- Documentation to the relevant quality management system and documentation to the ability to maintain the system and ensure compliance with the requirements (quality manual, quality objectives, organisational structure, methods of monitoring the quality system effectiveness, procedures for monitoring and verifying the product design, processes and methods for quality assurance in product manufacturing stages, tests and trials to be carried out before, during and after manufacture of the product etc.);
- Documentation guaranteeing that the manufacturer or importer is able to set up and maintain updated systematic procedures for collection and evaluation of data obtained from devices in the post-production phase, and to ensure implementation of any corrective measures. These measures shall also include the obligation to inform the competent authority immediately upon occurrence of an adverse event (the vigilance system).

- The technical documentation shall be clearly identified (title, number, date of issue, current version) and authorised – must contain name and signature of manufacturer’s authorised person.

7 Test samples

- In the framework of the conformity assessment process, the assessor of Notified Body No. 1023 may decide that it is necessary to submit product samples to allow inspection of the product appearance and its packaging, or to perform additional independent testing. In such case, the assessor contacts the Client to arrange conditions of sample delivery, including the amount of required samples.
- The Client usually takes samples in accordance with requested written or telephone instructions provided by the responsible employee of the Notified Body. In certain cases, however, the responsible person may decide that the samples shall be taken by the responsible employee of the Notified Body. Methods and conditions of sampling shall be agreed with the Client.
- The sample shall be taken including its intact packaging, which carries all the required information and warnings pursuant to MDD and GD 54.
- After completion of testing or inspections, samples shall be kept in the ITC archive for future reference (unless destructive testing was performed).
8 Contract

- The commercial relationship between the Client and ITC shall be arranged with respect to the nature, complexity and price level of the service - order.
- For orders of the Notified Body, contracts concluded with the Client shall include the following:
  - specification of the Contracting Parties
  - scope of contracted works (Subject Matter of the Contract)
  - price information and payment terms
  - delivery date of the service (Performance Period)
  - breach of contractual obligations and its consequences
  - rules for withdrawal from the contract
- Commencement of works is subject to bilateral written approval of the contractual conditions and settlement of the prepayment invoice. Advance payments are requested from all Clients, with exceptions laid down in special framework agreements on cooperation.

9 Scope of ITC notification

The system of ITC notification associated with MDD and GD 54 is provided at NANDO (New Approach Notified and Designated Organisations), see the following URL:

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=notifiedbody.notifiedbody&refe_cd=EPOS%5F46625

10 Legislation

The technical requirements for MD are contained in GD 54, which into the Czech legislation incorporates Council Directive 93/42/EEC on medical devices, as amended by the following EU legislative provisions:

- Commission Recommendation 2013/473/EU on audits and assessments carried out by the notified bodies in the area of medical devices

The wording of these European regulations is available in Czech and other languages of all the Member States of EU in the European database EUR-Lex at http://eur-lex.europa.eu/homepage.html.

11 Harmonized technical standards related to MD conformity assessment

If MD complies with provisions of the harmonized standards, which relate to it with respect to the specified purpose of use, then it meets the essential requirements of Annex No. 1 of GD 54. The overview of the harmonized standards for medical devices is extensive and its updated version is available on the website of the European Commission:


12 Conformity assessment of MD

12.1 General principles
Each MD must meet the essential requirements set out in Annex No. 1 of GD 54, which relate to it with respect to the specified purpose of use. Meeting the essential requirements is the basic prerequisite for a positive conformity assessment.

Compliance with the essential requirements shall be demonstrated by the manufacturer or manufacturer’s authorised representative to the Notified Body preferably in the form of a checklist.

### 12.2  MD classification

Medical devices are divided according to the degree of user's risk into Classes I, I sterile, I with measuring function, IIa, IIb and III. Classification of medical devices into individual Classes is realised by the manufacturer in accordance with the rules set out in Annex No. 9 of GD 54.

In addition to the above mentioned Annex No. 9, the following documents also serve as a methodological tool for MD classification:

- MEDDEV 2.4/1 Guidelines for the Classification of Medical Devices (as amended)
- MEDDEV 2.1/3 Borderline products, drug-delivery products and medical devices incorporating, as integral part, an ancillary medicinal substance or an ancillary human blood derivative (as amended)
- Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices (as amended)

In case of any dispute between the manufacturer and the Notified Body concerning the MD classification, the manufacturer is entitled to contact the State Institute for Drug Control (SUKL), which shall decide on request or ex officio in accordance with Section 9 (a) of Act No. 268/2014 Coll., on classification of medical devices. SUKL issues a decision for the manufacturer, which Notified Body No. 1023 of ITC shall unconditionally respect.

### 12.3  Procedures of MD conformity assessment

All medical devices referred to in Subsection 12.2 of the present Manual are subject to conformity assessment with participation of the Notified Body, with the exception of medical devices of Class I (involvement of the Notification Body in MD conformity assessment is thus required for Classes I sterile, I with measuring function, IIa, IIb and III).

The procedures for MD conformity assessment based on their classification are specified under Section 11 of GD 54 (Article 12 of MDD).

Selection of the conformity assessment procedure depends on the MD classification into particular Classes. If the applicant is unsure which procedure is suitable for particular MD conformity assessment, it is recommended to consult the issue with one of the experts listed in Part 2 of this Manual. The detailed description of the conformity assessment procedures is given in Annexes No. 2 to 7 of GD 54, and in Annexes II to VII of MDD.

### 12.4  Conformity assessment for MD systems and MD sets

In this case, conformity assessment is governed by the special procedure described in Section 5 of GD 54 (Article 12 of MDD), whereby the person assembling the medical devices bearing the CE marking and intending to place them on the market as a system or a set shall elaborate a declaration stating the following:

- mutual compatibility of the assembled medical devices has been verified in accordance with instructions of their manufacturer, and their operation in accordance with these instructions has been ensured,
- the system or set of medical devices has been packed and supplemented with corresponding information for users, including instructions of manufacturers for individual MD, and
- all the activities are subject to relevant methods of internal controls and inspections.
12.5 Conformity assessment for MD containing a substance considered to be a medicine

Medical devices containing as an integral part a substance which, if used separately, may be considered as a medicinal product, are included under Class III.

In addition to the standard MD conformity assessment procedure, it is necessary to take the following steps:

The manufacturer's procedures of monitoring and verifying the design of MD must contain a declaration whether the product contains or does not contain, as its integral part, a medicinal substance (and data on tests realised in this respect required to assess the safety, quality and usefulness of the substance taking into account the intended purpose of MD use). An ITC responsible person (expert) shall require, on behalf of the Notified Body (hereinafter referred to as “NB”), the European Medicines Agency (EMA) or the State Institute for Drug Control (SUKL) to issue a scientific opinion on the quality and safety of the substance, verify its usefulness within the MD with respect to its intended use (under Section 8.5 of Annex No. 1 of GD 54), and take the opinion of EMA/SUKL into account when assessing the MD conformity. If the scientific opinion of EMA/SUKL is negative, NB shall not issue the Certificate.

12.6 Conformity assessment process itself

a) The appointed team of investigators shall initiate the process of conformity assessment by examining the technical documentation.

b) Partial reports on examination of the technical documentation, review of the system documentation and review of clinical trial reports are prepared and sent to the manufacturer (Client), who is asked to supplement any missing information.

c) Completion of the technical documentation shall be done in the form of a new release (revision) of the technical documentation file.

d) Appointed employees of NB shall review the newly issued technical documentation file supplied by the manufacturer, and shall draw up a new report on the examination of the technical documentation.

e) If the newly issued technical documentation is incomplete or still contains errors and shortcomings, the manufacturer and NB shall continue in the process referred to in points b) to d) repeatedly.

f) The manufacturer has the maximum of 3 opportunities (rounds) to complete the relevant information and correct any errors.

g) If the Client submits all the required information and the product complies with the essential requirements, then the process shall advance to the next stage, which usually constitutes the Initial (Certification) Audit. However, if the Client fails to submit all the required information, and even the fourth edition of the technical documentation does not sufficiently demonstrate compliance with the requirements of GD 54 (MDD), then the investigator issues the Final Protocol with a negative conclusion (refusal to issue the Certificate).

h) The date of initiation of the Certification Audit shall be communicated to the manufacturer by the NB worker, who shall propose the team of auditors and submit the audit programme to the manufacturer. After the audit programme is approved and implemented, NB forwards the audit results to the manufacturer in the form of the "Audit Report of NB 1023". The Report contains an overview of any findings, including deadlines for their correction.

i) The manufacturer is obliged to respond to the identified findings, take measures to eliminate them within the agreed deadline, and notify NB of it in writing.

j) If necessary to verify conformity of MD with the requirements of GD 54, NB shall ensure relevant assessments and necessary testing of MD samples in own laboratories or in contracted laboratories of subcontractors.
k) Conclusions from the audit, test results and assessment of the documentation shall be summarised by the contract investigator into the Final Protocol containing the description of MD, test methods and test results (if part of the conformity assessment), the list of used documents issued by ITC or other entities, and unambiguous conclusions on MD conformity with the requirements of Directive 93/42/EEC, as amended, and GD 54.

l) The issuance or refusal to issue the Certificate is subject to approval at a meeting of the Decision Making Committee (meets twice per month) consisting of qualified professionals, who have not been involved in the process of assessment of the technical documentation or the audit.

m) If the decision under point l) is positive, NB 1023 shall issue the Certificate and the Final Protocol.

n) NB 1023 provides the Client with the above documents together with the "Acknowledgement of Receipt of Documents" (the signed version shall be sent by the Client back to ITC).

o) NB 1023 shall publish the issuance of the Certificate in the internet database under its administration, which is publicly accessible at the website http://www.itczlin.cz/cz/databaze-certifikatu-vyrobu-2.php.

p) If the decision under point l) is negative, NB 1023 refuses to issue the Certificate and shall inform the applicant in writing of the reasons which led to this decision. At the same time, the State Institute for Drug Control shall be informed of the reasons why the Certificate for the given product has been refused to the manufacturer.

12.7 Rules for recognition of results from the documentation submitted by the applicant

- Recognition of the results obtained in other laboratories and presented in the documentation depends solely on the decision of Notified Body No. 1023, which in no case disclaims its responsibility for the appropriate aspects of safety and functionality of assessed MD.
- As a rule, results given in test protocols by accredited laboratories are recognized on condition that no more than 3 years have elapsed from the date of issue of the Protocol.

13 Validity of Certificates issued by NB

- Geographical validity of Certificates is limited to the States of the European Economic Area (EEA) consisting of all Member States of the European Union and the states of EFTA, as well as to Switzerland (a bilateral agreement with the EU) and Turkey (the EU Customs Union).
- In accordance with MDD, Certificates and documents issued by NB 1023 are valid for a period not exceeding 5 years, and may be renewed for a further period no longer than 5 years based on an agreement concluded between the manufacturer and NB 1023.
- For re-certification, the manufacturer shall submit an application to NB 1023 at least 6 months in advance, and demonstrate the updated technical documentation.
- The validity of the issued documents is always conditioned by positive results of supervision audits at the manufacturer. Unless there is a change in the quality system, materials used or the production process of MD, the usual interval between individual supervisions is 1 year.

14 Inspection of medical devices subjected to conformity assessment

- If successful conformity assessment has been carried out, NB subsequently performs regular supervision of the manufacturer. NB performs periodically, in yearly intervals (unless specified otherwise), appropriate inspections and evaluations to make sure that the manufacturer uses the approved quality system, and provides the manufacturer, as a result of the inspection, with an assessment report. NB also realises unannounced inspections (see the General Framework
Agreement - GFA). The basis for an inspection is the “Supervision Agreement”. The technical secretariat elaborates a draft of the Agreement within a planned period, and sends it to the Client for confirmation. If the Client fails to return the signed Agreement within the given term, the validity of the Certificate is suspended following a written notice by NB 1023 (ITC). For unannounced inspections, the Agreement is submitted to the Client for signature on the spot at the start of the inspection. The team of assessors shall present the Command to Perform an Announced Audit, which is signed by a representative of the Notified Body and contains a list of authorised auditors and their identifying data.

- If there are any changes in the technological conditions of production, materials used or construction of MD, for which the Certificate has been issued, the manufacturer is required to inform NB 1023 (ITC) of this fact in writing.
- NB 1023 shall then assess whether the announced changes may lead to changes in safety parameters of MD and changes in fulfilment of the essential requirements under Annex No. 1 of MDD, and shall notify the Certificate holder in writing whether a reassessment of conformity is necessary or not.

15 Changes of already approved products to be reported immediately to NB 1023

- In accordance with the General Framework Agreement (GFA), the manufacturer is required to notify NB 1023 of any changes made to the product, which has been assessed by NB 1023 and has relevant EC Certificate and/or EC Certificate of Design Examination.
- Major changes are changes of the approved design, which may affect the conformity with the essential requirements of MDD (or GD 54), or the conditions prescribed for MD use. These are for example:
  - change in input material (including change of a supplier of material with the same specification),
  - change in the manufacturing technology,
  - change in the sterilization method for sterile products,
  - widening or narrowing of the intended purpose of use, or modification of its specification,
  - supplementation of warnings or conditions of product use in the Instructions for Use,
  - change in information on the label concerning conditions of storage or use,
  - relocation of the production plant to a new destination.
- Minor changes do not have a direct impact on the conformity with the essential requirements or the prescribed conditions for MD use. These are for example:
  - change in the name of the product, or adding the business name to the same product,
  - change in the registered office, modification of the manufacturer's name or identification address, by which the location of the production sites (plant) does not change,
  - change in the European authorised representative of the manufacturer,
  - modification of the graphical appearance of labels, instructions or packaging of the product without changing the information contained.

16 Procedure to be taken by the Client after obtaining documents from NB 1023

- After receiving the Certificate, the manufacturer or manufacturer’s authorised representative is entitled to put the certified product on the market and into service as soon as the obligations under MDD are met. MD may be placed on the market and into service if
  - conformity of its properties with the essential requirements was realised in the specified manner, and the outcome of such assessment was the finding that MD meets the essential requirements,
  - with the exception of custom built MD and MD intended for clinical trials, it is provided with the CE marking, design of which is governed by Regulation of the European Parliament and of the
Council (EC) No. 765/2008. The CE marking must be made in a visible, easily legible and indelible form either on the MD or its packaging,
- the manufacturer or manufacturer’s authorized representative has issued a written Declaration of Conformity in accordance with GD 54 and MDD,
- information on use is attached to it (in the Czech Republic, the information on use shall be in the Czech language) in accordance with point 17 of Annex No. 1 of GD 54 (point 13 of Annex I of MDD),
- it has been delivered and installed in a manner corresponding with its intended purpose.

- For purposes of bodies responsible for overseeing the market with medical devices (State Institute for Drug Control of the Czech Republic - SUKL), it is necessary to have available one copy of the same set of documents, which has been presented to NB for MD conformity assessment and accepted by the Notified Body. The MD manufacturer or manufacturer's authorized representative is obliged to store such documentation for at least 5 years (or at least 15 years in case of implantable MD) following the date of production of the last MD for purposes of the above supervisory authority.

16 Possible service extension by other activities provided by ITC

In addition to the notified services, ITC offers other services including:
- tests carried out in Accredited Testing Laboratories No. 1004 and 1004.3, and elaboration of relevant Test Protocol as a basis for conformity assessment in compliance with GD 54 (MDD);
- for products featuring a high quality level, ITC offers certification and a licence on affixing the ITC quality marking on each product (Certified Quality). The marking is usually accompanied with a text describing product characteristics.

The information on ITC quality marking are provided on the ITC website or can be obtained at the ITC Marketing Centre (phone +420 577 601 328).

17 Conclusion

This Manual for Clients governing MD conformity assessment is a comprehensive information source serving to ensure smooth process of conformity assessment. Particular procedures comply with guidelines and recommendations of NB-MED Group (European Coordination of Notified Bodies), which are available on the website http://www.itczlin.cz/itc.php?id=1042.

19 List of Annexes

Annex No. 1 – Definitions and abbreviations used
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Basic terms

**medical devices** - any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic or therapeutic purposes, and necessary for its proper application, intended by the manufacturer to be used for human beings for the following purposes:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for injury or handicap,
- investigation, replacement or modification of the anatomy or a physiological process,
- conception control,

and which does not achieve its principal intended effect in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Article 1 of MDD);

MDD does not apply to in vitro diagnostic medical devices and active implantable medical devices.

Pursuant to MDD (see Section 2, Subsection 3 of Act No. 268/2014 Coll.), medical devices do not further include:

- medicine, including medicinal products originating from human blood,
- beauty products,
- transplants, tissues or cells of human origin, and products containing tissues or cells of human origin or derived from them, with the exception of medical devices referred to in Article 1, Section 5 of MDD
- human blood, human blood products, plasma or blood cells of human origin, or medical devices containing at the time of their placement on the market such blood products, plasma or cells, with the exception of medical devices referred to in Article 1, Section 4a of MDD, and Section 2, Subsection 2 (f) of the Act on Medical Devices,
- personal protective means,
- transplants, tissues or cells of animal origin, unless the device is manufactured utilizing non-viable animal tissue or non-viable products derived from animal tissue.

**CE marking** – a marking placed on a product or its packaging, by which the manufacturer confirms conformity of its properties with the requirements of relevant Directive or Government Decree.

**essential requirements** – technical requirements for products, meeting of which is a prerequisite for the minimum sufficient safety of the product when used in a usual and reasonably foreseeable manner. Essential requirements are defined in Directives applicable to the given product area and implemented into the national legislation of the EU Member States. Meeting of the essential requirements is a decisive aspect of all the conformity assessment procedures. The most frequent method of demonstrating conformity with the essential requirements is by compliance with the harmonized standards related to the product.

**notified body** – a body authorised to defined activities in conformity assessment of products specified by a national authority (in Czech Republic it is the Office for Standards, Metrology and Testing - UNMZ), and notified to authorities of the European Commission and all the EU Member States as a body authorised to conduct activities in conformity assessment of products, for which the notification has been received. Decisions and documents issued by all notified bodies (NB) are equal and valid in all the states of EU, EFTA, in Turkey and Switzerland.

**conformity assessment procedure** – a method defined by specific Directive or Government Decree, by which the manufacturer demonstrates compliance of product properties with the essential requirements,
usually in the presence of a Notified Body. Usually, the manufacturer is free to choose from several conformity assessment procedures (referred to as modules).

**notification scope** – specific definition of the range of products and conformity assessment procedures, for which the given NB is notified and authorized to conduct its activities on the basis of demonstrated professional and technical competence.

**manufacturer** – a natural or legal person, who designs, manufactures, packs and/or labels medical devices and is responsible for these prior to their placement on the market, realises such activities under its own company name or title, regardless of whether performed so by itself or on behalf of a third entity, who has a written authorisation of the manufacturer to act on manufacturer’s behalf, taking into account the requirements given for the manufacturer under Act No. 268/2014 Coll., on medical devices, as amended.

**authorized representative** - any natural or legal person established in any EU Member State, who is explicitly authorised by the manufacturer to act on manufacturer’s behalf to ensure compliance with requirements of relevant directives (and their implementation into national legislations of relevant Member States) imposed on the manufacturer.

**placement on the market** - a moment when medical devices are first submitted or offered for distribution or use in the European Union in return for payment or free of charge, or when ownership rights are first assigned to them, unless a special law states otherwise.

**Abbreviations used**

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<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>ATL</td>
<td>Accredited testing laboratory</td>
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<td>EFTA</td>
<td>European Free Trade Association</td>
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<tr>
<td>Directive</td>
<td>For the purposes of this Manual, it is the New Approach Directive laying down technical requirements for the given product area</td>
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<td>ITC</td>
<td>Institute for Testing and Certification, joint-stock company</td>
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<td>NB</td>
<td>Notified body</td>
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<tr>
<td>NB 1023</td>
<td>Notified Body No. 1023 (a designation assigned to ITC by the European Commission)</td>
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<tr>
<td>GD</td>
<td>Government decree</td>
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<tr>
<td>GD 54</td>
<td>Government Decree No. 54/2015 Coll., on technical requirements for medical devices</td>
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<tr>
<td>MDD</td>
<td>The abbreviation refers to Directive 93/42/EEC above</td>
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<td>UNMZ</td>
<td>Czech Office for Standards, Metrology and Testing</td>
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<tr>
<td>Act No. 22</td>
<td>Act No. 22/1997 Coll., on technical requirements for products and changes and amendments to certain laws, as amended</td>
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<tr>
<td>MD</td>
<td>Medical devices</td>
</tr>
</tbody>
</table>