



INSTITUTE FOR TESTING AND CERTIFICATION, a. s.
Quality system certified according to EN ISO 9001:2000

Authorized Body 224 * Notified Body 1023 * Accredited Testing Laboratory * Accredited Calibration Laboratory * Accredited Certification Body

Manual for ITC's clients

**for conformity assessment of active implantable medical devices
pursuant to Article 9 of Council Directive 90/385/EEC and Section
10 of Czech Republic's Government Order No. 154/2004, Collection
of Laws**

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1. Introduction

The present Manual aims at informing customers of the Institute for Testing and Certification, a.s. (hereinafter referred to as „ITC“) about their rights and obligations in conformity assessment procedure of active implantable active implantable medical devices (hereinafter referred to as AIAIMD) with a Notified Body complicity in.

ITC is a legal entity authorized to perform activities in conformity assessment of AIAIMDs placed on the markets of member states of the European Union and countries of the European Free Trade Association and notified for this activity by the European Commission as Notified Body No. 1023 (hereinafter referred to as only „NB 1023“).

Technical requirements on AIAIMDs and obligations of persons introducing a AIAIMD into the market of the European Union are laid down by the Council Directive 90/385/EEC as amended. In compliance with legislation of the European Union this Directive is implemented into the Czech legislation in the form of a *Czech Republic's Government Order No. 154/2004, Collection of Laws, which lays down technical requirements for active implantable active implantable medical devices* (hereinafter referred to as only „GO 154“).

Practically it means that by meeting the requirements laid down by the GO 154 also requirements of the above directive are met at the same time and the product whose conformity with these requirements has been assessed by an authorized representative in co-operation with NB 1023 (ITC) may be placed on the market of all EU and EFTA member states without any further restrictions and measures taken.

2. Definitions

2.1. Basic terms

- **active implantable medical device** means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by intervention into a natural orifice, and which is intended to remain after the procedure (definition see Article 1, Section 2 (c) AIAAIMDD and Section 2, Subsection 2 (f) of Czech Active implantable medical devices Act No. 123/2000, Collection of Laws, as amended);
- **European CE marking of conformity** means a marking placed on a product or its package by which the manufacturer confirms conformity of its properties with requirements of the appropriate Directive and GO;
- **essential requirements** means technical requirements for products the meeting of which is a prerequisite for a minimum sufficient safety of a product provided they are used in a usual and reasonably foreseeable manner. They are defined in the Directives related to the given product area and implemented into national legislation of the EU member states. Meeting of the essential requirements is a decisive aspect of all conformity assessment procedures. The most frequent method of demonstration of the conformity with the essential requirements is

a demonstration of conformity with the harmonized standard related to the product;

- **harmonized Czech technical standard** means a Czech technical standard which fully adopts requirements of the harmonized European standard. Meeting requirements of a harmonized Czech or European standard is considered within their scope as meeting of appropriate essential requirements of the Directives and the Government Order related to a given product,
- **notified body** means a body authorised to defined activities in conformity assessment of products specified by a national authority (in case of the Czech Republic by Úřad pro technickou normalizaci, metrologii a státní zkušebnictví – ÚNMZ / Czech Office for Standards, Metrology and Testing) and notified to European Commission bodies and to all EU member states as a body authorised to carry out activities in conformity assessment of products for which it received the notification. Decisions and documents issued by all notified bodies (NB) are equal and valid in the entire EU;
- **conformity assessment procedure** means a method defined by a directive or a GO by which the manufacturer demonstrates conformity of the product properties with essential requirements, usually in the presence of a notified body. Usually, the manufacturer is free to choose between several conformity assessment procedures (known as modules);
- **notification scope** means a specific definition of the range of products and conformity assessment procedures for which the given NB, based on a demonstration of a professional and technical competence, is notified and authorized to conduct its activities;
- **manufacturer** means the natural or legal person with responsibility for the design, manufacture, 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 that person himself or on his behalf by a third party;
- **authorized representative** means any natural or legal person established in the EU who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies in the EU instead of the manufacturer with regard to the latter's obligations under the Directive 90/385/EEC as amended;
- **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 and/or in promotional materials;
- **placing on the market** means the first making available in return for payment or free of charge of a device other than a device intended for clinical investigation, with a view to distribution and / or use on the EU market, regardless of whether it is new or fully refurbished;

2.2. Abbreviations used

ATL	Accredited testing laboratory
AIAIIMDD	For the purposes of this Manual the Council Directive 90/385/EEC which lays down technical requirements on Active Implantable Active implantable medical devices
ITC	Institut pro testování a certifikaci, a.s. (Institute for Testing and Certification)
NB	Notified Body
NB 1023	Notified Body 1023 (this designation has been assigned to ITC by the European Commission)
GO	Czech Government Order
GO 154	Czech Republic's Government Order No. 154/2004, Collection of Laws as amended, setting out technical requirements on Active Implantable Active implantable medical devices
COSMT	Czech Office for Standards, Metrology and Testing
Act 22	Czech Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing certain laws, as amended
AIAIMD	Active Implantable Medical device

3. Scope of ITC's notification

ITC's notification in the area of the Council Directive 90/385/EEC and GO 154 covers AIAIMDs and conformity assessment procedures pursuant to Article 9 of the AIAIIMDD. The scope of the notification has been set out by the COSMT's Decision.

4. Legislation

4.1. Act 22/1997, Collection of Laws, and GO 154/2004, Collection of Laws

The legislation framework for conformity assessment of specified products is formed by the Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing certain laws, as amended. AIAIMDs are specified products in the sense of Section 12, Subsection 1 of the Act 22. Technical requirements for AIAIMDs are contained at a general level in the law and made specific in the GO 154, which implements requirements of the Directive 90/385/EEC as amended into the Czech legislation. In the meaning of the EU law, the fulfilment of the Czech legislation means also fulfilment of appropriate directive (AIAIIMDD) requirements.

5. Harmonized technical standards related to conformity assessment of active implantable active implantable medical devices

If a active implantable medical device is in conformity with harmonized standards related thereto with respect to the specified purpose of use, then it meets essential requirements of Annex I of the AIAIMDD. A survey of harmonized standards for active implantable active implantable medical devices is extensive and an up-dated version can be found on web pages of the European Commission

<http://ec.europa.eu/enterprise/newapproach/standardization/harmstds/reflist/implmedd.html>

6. Conformity assessment of AIMD

6.1 General principles

Each of AIMDs must meet essential requirements set out in Annex I to AIMDD related to this device with respect to its intended purpose of use. Meeting of the essential requirements is the basic prerequisite of conformity assessment.

By presenting a checklist the manufacturer or his authorized representative shall demonstrate to the notified body that the essential requirements have been met.

Following document serves a methodical aid in addition to inclusion of active implantable medical devices into scope of the AIMDD.

- MEDDEV 2.1/3 Rev. 2 Demarcation between Directive 90/385/EEC on Active Implantable Medical Devices, Directive 93/42/EEC on Medical Devices and Directive 65/65/EEC (replaced by Directive 2001/83/EC) Relating to Medicinal Products and Related Directives.

6.2 Procedures for conformity assessment of active implantable medical devices

All active implantable medical devices are subject to conformity assessment with a notified body complicity in. Procedures for conformity assessment of active implantable medical devices are specified in Article 9 of the AIMDD.

In the present Manual two separate sections, namely Sections 7.1 are devoted to conformity assessment procedure for active implantable medical devices containing tissues of animal origin.

7 Selection of conformity assessment procedure

The choice of a conformity assessment procedure depends on manufacturer's decision. The following table gives procedures that can be used in assessing conformity of active implantable medical devices. Should the client not be sure which of the procedures available is suitable a consultation with an expert is recommended (see Section 8.1 of this Manual).

Table 1 – Selection of a conformity assessment procedure depending on the Class of the medical device

Annex to AIMDD	Manufacturer's activity	Notified Body's activity <i>Document issued</i>
2 (including Section 4.)	preparation of documentation according to Section 3. of <u>Annex 2</u> description of the design according to Section 4.2. and ensuring conformity with requirements of this Annex	design review according to Section 4. of <u>Annex 2</u> <i>EC Design-examination certificate</i> assessment of full quality system according to <u>Annex 2</u> (by an audit at the manufacturer's premises) <i>EC Certificate</i> surveillance according to Section 5. of Annex 2 <i>Assessment Report</i>

Annex to AIMDD	Manufacturer's activity	Notified Body's activity <i>Document issued</i>
3 plus 4	preparation of technical documentation according to Section 3. of <u>Annex 3</u> and ensuring conformity with requirements of Annexes 3 and 4	examination of type <u>according to Annex 3</u> EC type-examination certificate verification of conformity of each piece produced; the verification is done according to Section 5. or on a statistically (randomly) selected sample according to Section 6. of <u>Annex 4</u> EC Certificate of Conformity of each AIMD EC Certificate of Conformity of batch (lot)
3 plus 5	preparation of technical documentation according to Section 3. of <u>Annex 3</u> and Section 3. of <u>Annex 5</u> and ensuring conformity with requirements of Annexes 3 and 5	examination of type <u>according to Annex 3</u> EC type-examination certificate assessment of production quality system according to <u>Annex 5</u> (by an audit of the manufacturer's operational spaces) EC Certificate surveillance according to Section 4. of Annex 5 Assessment Report

7.1 Conformity assessment for active implantable medical devices containing tissues of animal origin

The procedure for conformity assessment of active implantable medical devices containing tissues of animal origin derived from some kinds of cattle, sheep or goats, and further from deer, elks, minks and cats is specified in the Directive 2003/32/EC. In conformity assessment of such AIMD proceeded according to one of the possibilities given for active implantable medical devices in Table 1. An additional requirement, which must be documented, is elaboration of specifications established in Risk Analysis and Risk Control. Notified bodies appraise the manufacturer's strategy in risk analysis and risk management, particularly

- the information supplied by the manufacturer,
- reasons given for use of the tissues or derivatives of animal origin,
- results of elimination or deactivation studies or searches of technical literature,
- inspection of suppliers, original materials and final products conducted by the manufacturer
- the necessity to verify the origin of the initial materials, including deliveries from manufacturer's suppliers.

In order to ensure a professional assessment of active implantable medical devices containing tissues of animal origin a contract between ITC and Státní veterinární ústav (State Veterinary Institute) in Jihlava, Czech Republic, was concluded. At this Institute, Národní referenční laboratoř pro diagnostiku BSE a animálních transmisivních encefalopatií (National Reference Laboratory for Diagnostics of BSE and Animal Transmissible Encephalopathies) accredited as Testing Laboratory AZL 1129 by Český institut pro akreditaci (Czech Accreditation Institute) was established

in compliance with the Decree 298/2003, Collection of Laws, and Section 78 of Act 166/1999, Collection of Laws, as amended.

Before lodging an application for conformity assessment for these active implantable medical devices, a consultation with an expert is recommended – see the contact information in Section 8.1 of this Manual.

8 Notified Body's procedures for conformity assessment of an active implantable medical device

This section describes steps that the manufacturer or his authorized representative must take in assessing conformity of the active implantable medical device.

For an easier distinction the activities of a person requesting the Notified Body 1023 (ITC) for a conformity assessment are described in a common typeface while responses and activities of NB 1023 are graphically differentiated by italics.

8.1. Application

8.1.1. The manufacturer of an active implantable medical device or its authorized representative (hereinafter referred to as “client”) lodges an application for conformity assessment with the Notified Body 1023 using a form, which is an Addendum 1 to this Manual. The client will deliver the completed form personally or by mail to a contact person as follows:

- a) Dipl. Ing. Václav Kahánek (Department of Medical Device Conformity Assessment)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Czech Republic
tel. +420 577 601 357, fax. +420 577 104 855, e-mail: ykahanek@itczlin.cz

- b) Jana Balusková (Department of Medical Device Conformity Assessment)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Česká republika
tel. +420 577 601 269, fax. +420 577 104 855, e-mail: ibaluskova@itczlin.cz

- c) Daniela Hvoždová (secretariat of manager of Certification Division)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
764 21 Zlín
Česká republika
tel. +420 577 601 263, fax. +420 577 104 855, e-mail: dhvozdova@itczlin.cz

The application form can also be obtained by downloading the appropriate file from ITC's web site (home page www.itczlin.cz gradually using menu >Certification of Product >Conformity Assessment >Active implantable medical devices >Application Form or at the request from the above contact persons who will send it by fax or e-

mail. Client may send the application to ITC using also his/her own form on condition that the client's form will contain all data specified in the ITC's official application form.

8.1.2. Already at this stage it is required to supply with the application also documentation in compliance with the appropriate Annex the AIMDD. **The table in Annex 2 of the present Manual giving a common list of desired items of documentation serves as a methodical aid for compilation of the full set of documents necessary for conformity assessment.** If the conformity assessment includes procedures according to Annexes 3 and 4, it is suitable, on agreement with an expert, to supply also samples of the active implantable medical device to be assessed.

8.1.3. The application and the documentation presented must be in either Czech or English. Use of other languages of the European Union is possible only on agreement with the above expert. In relation to Article 4, Section 4. the AIMDD the information on use of the medical device to be placed on the Czech market must be **in the Czech language.**

Filling in of the application form can be consulted, in case of an ambiguity, with the persons at the above contact addresses.

8.1.4. Neither the Directive 90/385/EEC nor the Act 22 make possible for the manufacturer or his authorized representative to lodge the application for conformity assessment of the same active implantable medical device with additional notified bodies.

8.2. Application review

8.2.1. The notified body is obliged under the law to respond to client's request for a service concerning conformity assessment within 20 days at the latest. The certification worker of NB 1023 (ITC) will register the application and reviews at this stage correctness and completeness of the application data or correctness of selection and number of samples supplied.

8.2.2. If the application or the documentation is incomplete, the certification worker will specify in writing (by letter, e-mail, fax) the missing items and request their completion.

8.3. Draft conformity assessment contract

8.3.1. Prior to drawing up of the contract the notified body will specify the procedure it will use in the process of conformity assessment, if it is necessary to do additional tests and if so, what the extent of the tests will be and where/by whom they will be done.

8.3.2. NB 1023 will make a price proposal including price for the audit (if needed), price of the necessary tests and of other certification activities and will elaborate a draft of the contract (a sample of such a contract draft is shown in Annex 3 to the Manual). Secretariat of the Notified Body will send the draft of the contract signed by a representative of NB 1023 or his deputy to the applicant for approval and signing

by a person authorized to act on his behalf. Simultaneously with the contract the NB will send the applicant also the invoice for advance payment, unless agreed exceptionally otherwise.

8.3.3. The expert of NB 1023 will discuss client's comments, if any, on the wording of the draft contract with the manager of the Certification Division. Based on acceptable comments a definitive wording of the contract draft will be elaborated. The NB 1023 representative will sign the contract draft and the secretariat will send it to the applicant for consent.

8.3.4. Provided the applicant's comments are unacceptable and personal negotiation is not successful the contract will not be concluded and NB 1023 secretariat will notify the applicant thereof.

8.3.5. Continuation of the conformity assessment process, particularly start of the tests and assessment, is subject to applicant's consent to the price proposal, content of the contract and this Manual. The company will express its consent by signing the draft contract and paying the advance invoices. A necessary prerequisite for starting the activity is also supply of a sufficient quantity of samples, if needed for the assessment.

8.4. Sampling

8.4.1. If the conformity assessment pursuant to AIMDD includes the procedure according one of **the Annexes 3 and 4**, it is suitable for the client to deliver a sample of the AIMD together with the application for assessment. Since the testing of the AIMD itself depends very much on its type and character, it is suitable to consult sampling with the expert in advance. When agreed, the samples can be provided also additionally; however, this will extend the period of time necessary to carry out the conformity assessment.

8.4.2. The client usually takes the samples according to requested written or phone instructions provided by the responsible worker of NB 1023. However, the client can ask the ITC's certification personnel for this service under usual commercial terms.

8.4.3. The sample is taken including its intact package, on which warnings and all other information required by the Directive 90/385/EEC and GO 154 are provided.

8.5. Conformity assessment process itself

8.5.1. For the purpose of an audit will be carried out at the manufacturer's premises, the NB suggests a team of auditors (comprising usually a lead auditor and a technical expert) and submits an audit programme to the manufacturer. After the manufacturer gave his consent to the audit and when the audit has been completed the NB hands over the audit results to the manufacturer in the form of an "Audit Report". The Report contains a survey of non-conformities, if any, and the term during which they must be eliminated.

8.5.2. The manufacturer is obliged to respond to the non-conformities found, to take measures within an agreed period of time and notify the NB thereof in writing.

8.5.3. *If needed, the NB assures appropriate assessments and necessary tests of the AIMD samples in its own laboratories or in contractual accredited laboratories approved by the COSMT.*

8.5.4. *Conclusions from the audit, test results and assessment of the documentation will be summed up by the certification worker into a Final Report containing description of the AIMD, description of the test method utilized and test results obtained (provided they are a part of the conformity assessment), a list of documents issued by ITC or other entities and used in the conformity assessment and unambiguous conclusions on conformity of the AIMD with requirements of the Directive 90/385/EEC.*

8.5.5. *If the conclusions are positive, the NB 1023 will draw up a Certificate (see the survey of the issued certificates in the Table 1 of the present Manual), an integral part of which is the appropriate Final Report, and hands it over to the Applicant under the conditions laid down in the Conformity Assessment Contract.*

8.5.6. *The NB 1023 will publish the issuance of the Certificate in the internet database, which it administers on its publicly accessible pages at www.itczlin.cz.*

8.5.7. *If it is ascertained during the conformity assessment process that the AIMD fails to meet the requirements related thereto with respect to its intended purpose, the NB 1023 will refuse to draw up the Certificate and will inform the applicant in writing about the reasons which led it to this decision.*

8.6. Rules for recognition of results from the documentation submitted by the applicant

8.6.1. *Recognition of the results obtained by other laboratories and presented in the documentation depends solely on the decision of NB 1023, which in no case disclaims its responsibility for the appropriate aspect of safety of the AIMD assessed.*

8.6.2. *As a rule, results given in test reports by accredited laboratories are recognized on condition that no more than 3 years have elapsed from the date of issue of the report.*

8.6.3. *In principle, results of tests carried out by manufacturer's or non-accredited laboratories are not recognized. Tests performed on unique testing equipment not commonly accessible and tests conducted by means of validated analytical/physical test methods the implementation of which would be difficult at AZL, may constitute an exception.*

8.7. Validity of Certificates drawn up by the NB

8.7.1. *Geographical validity of the certificates is given by the number of countries that implemented the Directive 90/385/EEC into their legislation and allow placement of CE-marked products on their own markets. They are primarily member states of the EU and ESVO.*

8.7.2. *In compliance with the AIMDD the certificates and documents issued by NB 1023 (ITC) expire after 5 years at the latest but can be extended to further 5 years*

based on manufacturer's application lodged in the period of time stipulated in the contract between the manufacturer and NB 1023. However, the validity of the documents is subject to a regular surveillance audit conducted at the manufacturer's premises. Should no change in the quality system, material used and manufacturing process of the AIMD be made, the usual interval between the inspections is one year.

9. Inspection of conformity assessed active implantable medical devices

9.1. If the conformity assessment was carried out successfully the NB conducts a regular surveillance at the manufacturer's and/or his authorized representative's premises. The 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, an assessment report. The NB may also, at its discretion, conduct inspections not announced in advance. The basis for the inspection is "Inspection Contract". The technical secretariat will elaborate a draft of the contract within a planned period of time and sends it the customer for confirmation. Should the customer fail to return the signed contract within a given term the validity of the Certificate is suspended following a written notice by the NB 1023 (ITC).

9.2. If the technological conditions of the manufacture and materials used are changed or the design of the AIMD for which the Certificate has been issued is modified the manufacturer is obliged to notify the NB 1023 (ITC) of this fact in writing.

9.3. Thereafter, the NB 1023 will consider whether the announced changes can lead to changes of safety parameters of the AIMD and to changes in meeting the essential requirements of the Annex 1 of the AIMDD and inform in writing the certificate holder whether or not a new conformity assessment is necessary.

9.4. The NB 1023 personnel will notify in writing the certificate holder of a change in the legislation or harmonized standards concerning the assessed product and the certificates issued.

10. Procedure to be taken by the Client after procurement of NB 1023 documents

10.1. Following procurement of the NB Certificate, the manufacturer or his authorized representative has the right to place the certified product on the market and put it into service as soon as he fulfils the obligations imposed on him by requirements of the AIMDD. The AIMD may be placed on the market and put into service if

- conformity of its properties with the essential requirements was carried out in the specified manner and if the outcome of this assessment was the finding that the AIMD met the essential requirements;
- the AIMD is provided (with the exception of a custom-made device) with the European CE conformity marking, the graphical form of which will be specified by the GO 291/2000, Collection of Laws, and the Directive 93/68/EEC. The CE marking must be made in a visible, easily legible and indelible form on the medical device or its pack;

- the manufacturer or his authorized representative has made a written declaration (Declaration of Conformity) pursuant to appropriate conformity assessment procedure applied;
- information on its used has been attached to the AIMD (in the Czech Republic the information on its use must be in the Czech language);
- the AIMD has been delivered and installed in a corresponding manner in compliance with its intended purpose.

10.2. For purposes of bodies responsible for surveillance of the market (Česká obchodní inspekce /ČOI/ /Czech Commercial Inspection/ in the Czech Republic) and of active implantable medical devices (Státní ústav pro kontrolu léčiv SÚKL /State Institute for Drug Control/ in the Czech Republic) the same set of documents as that submitted to the NB for the assessment of conformity of the AIMD with the requirements of AIMDD must be available. The manufacturer shall store the documentation for at least 5 years following manufacture of the last AIMD for the need of the above state administration authorities.

11. Extension of the service with other services provided by ITC

In addition to the notified services ITC offers other services including:

- tests carried out by the Accredited Testing Laboratory 1004 and elaboration of the appropriate Test Report as a basis for conformity assessment in compliance with the AIMDD;
- in products featuring a high quality level, certification and issue of a licence on affixing ITC quality marking (ITC Certified Quality) on each product. The marking is usually accompanied with a text describing product characteristics;
- certification and granting of a licence for use of the marking of conformity with the Czech technical standard “ČSN Test” demonstrating a permanent conformity with ČSN, ČSN EN, ČSN ISO and other standards.

The information on ITC quality marking and ČSN Test markings are given on ITC's web pages or can be obtained from the secretariat of ITC's Certification Division (phone +420 577 601 623).

12. Conclusion

This Manual for clients of AIMD conformity assessment is a comprehensive information source serving to a smooth conformity assessment process.

Particular procedures to relevant device follow “Guidelines” and “Recommendations” of NB-MED (European Co-ordination of Notified Bodies) available on web site

http://europa.eu.int/comm/enterprise/medical_devices/implementation_en.htm