CONFORMITY ASSESSMENT OF MEDICAL DEVICES

MANUAL FOR CLIENTS

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

WWW.ITCZLIN.CZ

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Prepared by: Ing. Pavla Heinzová
Approved by: Ing. Pavel Vaněk
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1. INTRODUCTION

The present Manual aims to inform customers of the Institute for Testing and Certification (hereinafter referred to as only “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 (hereinafter referred to as only “NB 1023”)

Based on the decision of UNMZ (Czech Office for Standards, Metrology and Testing) ITC is authorized as NB 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 NB 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 NB 1023.

The questionnaire form is available for download on the ITC website:
www.itczlin.cz/en/certification-medical-devices-ce-itc

The Client shall send the completed questionnaire either personally, by post or e-mail to one of the contacts below:

Institute for Testing and Certification
Department of Certification of Medical Devices

a) **Jana Balusková**
trida Tomase Bati 5264, building 113, Svit area, 760 01 Zlin, Czech Republic
phone: +420 572 779 953
e-mail: jbaluskova@itczlin.cz

b) **Markéta Klinkovská**
trida Tomase Bati 5264, building 113, Svit area, 760 01 Zlin, Czech Republic
phone +420 572 779 954
e-mail: mklinkovska@itczlin.cz

- 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.
- 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 or letter) 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
- Upon delivery of the duly completed application and full technical documentation to the address of NB 1023, the Client becomes the applicant and his application becomes a regular order. Together with the application, NB 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: www.itczlin.cz/en/certification-medical-devices-ce-itc
- The EU legislation does not allow the manufacturer or manufacturer's authorized representative to file an application for service of an authorized or NB 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) 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 service price and delivery date are usually calculated after providing all the details necessary for specification of the range of expert works, for example technical documentation.

6. CONTRACT

The commercial relationship between the Client and ITC shall be arranged with respect to the complexity and price level of the service - order.

For orders of the NB, 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.

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 NB 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.

8. 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 no longer than 5 years. For re-certification, the manufacturer shall submit an application to NB 1023 at least 9 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.

9. INSPECTION OF MEDICAL DEVICES SUBJECTED TO CONFORMITY ASSESSMENT

If successful conformity assessment has been carried out, NB 1023 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 realizes 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).

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.

10. 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 www.itczlin.cz