CONFORMITY ASSESSMENT OF IN VITRO DIAGNOSTIC MEDICAL DEVICES

MANUAL FOR CLIENTS

INSTITUTE FOR TESTING AND CERTIFICATION, Inc.

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Effective from: 7. 2. 2019
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Manual´s version: 2

Date of issue: 7. 2. 2019
Place of issue: Zlín

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 in vitro medical devices (hereinafter referred to as “IVD”) with NB 1023.

Based on the decision of UNMZ (Czech Office for Standards, Metrology and Testing), ITC is authorized as NB 1023 (hereinafter referred to as "NB 1023") to perform activities in conformity assessment of IVD placed on the markets of member states of the European Union and countries of the European Free Trade Association (EFTA).

The technical requirements for IVD and obligations of persons introducing IVDD on the markets are laid down by European Directive 98/79/EC on in vitro diagnostic medical devices, as amended (hereinafter referred to as "IVDD"). In compliance with the legislation of the European Union, this Directive is implemented into the Czech legislation in the form of Government Decree No. 56/2015 Coll. (hereinafter referred to as "GD 56") on technical requirements for IVDD.

In practical terms it means that, by meeting the requirements laid down by GD 56, the requirements of the above Directive are also met, and the product, for which these requirements has been assessed by the manufacturer or manufacturer’s authorized representative in cooperation with NB 1023, 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 IVD 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-in-vitro-diagnostic-medical-devices-ce-itc

The Client shall send the completed questionnaire either personally, by post or by e-mail:

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 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) 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, the Client shall submit the formal application for conformity assessment of in vitro diagnostic medical devices with the technical documentation.
- 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 and the required documentation shall be submitted either in Czech, Slovak and/or English.
- 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 or 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. TEST SAMPLES

- In the framework of the conformity assessment process, the assessor of NB 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 IVDD and GD 56.

7. CONTRACT

- The commercial relationship between the Client and ITC shall be arranged with respect to 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.

8. 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 IVD.

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.

In case of EC procedure of type assessment or EC verification under Annexes No. 5 and 6 of GD 56, results of tests carried out in manufacture's or non-accredited laboratories are not recognized. An exception may be permitted for tests performed on a unique testing equipment, which is not commonly accessible under the direct supervision of the NB expert overseeing the test conditions and participating in the processing of test results.

9. 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 the IVDD Certificates and documents issued by NB 1023 (ITC) are valid for a period not exceeding 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 IVD, the usual interval between individual supervisions is 1 year.

10. INSPECTION OF IN VITRO DIAGNOSTIC 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).

If there are any changes in the technological conditions of production, materials used or intended use (functionality) of in vitro diagnostic medical devices, 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 functional parameters of IVD and changes in fulfilment of the essential requirements under Annex No. 1 of IVDD, and shall notify the Certificate holder in writing whether a reassessment of conformity is necessary or not.

11. RELEASE OF DOSES (BATCHES) OF IN VITRO DIAGNOSTIC MEDICAL DEVICES FROM LIST A

Each production dose (batch) of in vitro diagnostic medical devices included on List A of Annex II of IVDD, or List A of Annex No. 2 of GD 56, is subject to the process of product verification, in which the Notified Body shall be involved. Any production batch, which has not undergone the verification process (commonly referred to as the "Batch Release"), may not be put on the market.

The criteria for the release of produced IVD batches stated on List A, including the reference methods and materials, are referred to in Commission Decision 2002/364/EC on common technical specifications for in vitro diagnostic medical devices, as amended by Commission Decisions 2009/108/EC, 2009/886/EC and 2011/869/EU. The Common Technical Specification is commonly abbreviated to CTS.

Without delay after completion of the inspections and tests, the manufacturer shall provide to NB relevant reports on these tests realised for each produced IVD or IVD batch.

The manufacturer is obliged to provide samples of manufactured IVD or produced IVD batches to NB in accordance with the pre-agreed conditions and procedures (see GFA).

The manufacturer may place in vitro diagnostic medical devices on the market, unless the Notified Body announces another decision to the manufacturer within the period no longer than 30 days after receipt of the samples, including, in particular, any conditions of validity applicable to the issued Certificates.

For the release of each produced dose (batch), it is necessary to substantiate the following documents to NB:

- Application (official letter) of the manufacturer related to the produced IVD batch (product name, catalogue number, batch number, expiry date and batch volume, i.e. the quantity of IVD sets in the given batch);
- Copies of production records with all the information on input materials, input inspections, in-process inspections, etc.;
- Test results for the given production batch of IVD carried out in the scope and manner laid down by CTS;
- Sample of the produced IVD (at least one IVD set) in the final intact packaging with appropriate markings, including the documentation in the state in which it shall be put on the EU market;
- The sample shall be delivered to ITC in a way determined for this IVD by the manufacturer (compliance with the shipment conditions, such as minimum and maximum temperature, pressure, humidity, etc.).

An appointed worker of NB 1023 examines the state of the delivered sample in terms of its compliance with the technical documentation, and reviews the test results in terms of their compliance with the requirements of CTS.

If the result is positive, NB 1023 shall issue a written Decision on Batch Release within 30 days. Upon its receipt, the manufacturer is entitled to put the particular batch on the market.

If the test results or the testing scope are not in compliance with relevant provisions of CTS and the approved technical documentation of the manufacturer, NB 1023 shall reject the batch release and shall communicate such decision to the manufacturer in writing. The manufacturer is not entitled to put any rejected batch on the market.

If a batch is rejected repeatedly, NB 1023 shall suspend validity of the Certificate and shall ask the manufacturer to implement corrective measures to ensure homogeneous quality of production batches.

12. CONCLUSION

This Manual for Clients governing IVD 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/itc.php?id=1042.