# Manual for ITC's clients

## from the area of conformity assessment of in vitro diagnostic medical devices pursuant to Article 9 of Council Directive 98/79/EC and Section 8 of Czech Republic's Government Order No. 453/2004, Collection of Laws

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**Approved by:**

Dipl. Ing. Pavel Vaněk
Director of Certification Division

## 1. Introduction

The present Manual aims at informing customers of Institut pro testování a certifikaci, a.s. (Institute for Testing and Certification) (hereinafter referred to as only „ITC“) about their rights and obligations arising from co-operation in conformity assessment of in vitro diagnostic medical devices (hereinafter referred to as only IVD).

ITC is a legal entity authorized 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) and notified for this activity by the European Commission as Notified Body No. 1023 (hereinafter referred to as only „NB 1023“).

Technical requirements for IVD and obligations of persons introducing in vitro diagnostic medical devices into the market of the European Union are laid down by the European Directive 98/79/EC 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. 453/2004, Collection of Laws, which lays down technical requirements for in vitro diagnostic medical devices* (hereinafter referred to as only „GO 453“).

Practically it means that by meeting the requirements laid down by the GO 453 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 introduced into the market of all EU and EFTA member states without any further restrictions and measures taken.

## 2. Definitions

### *2.1. Basic terms*

**- in vitro diagnostic medical device** means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information concerning a physiological or pathological state, or a congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures. Also, specimen receptacles, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination, are considered to be in vitro diagnostic medical devices.

Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination (definitions see Section 2, Subsection 2, letter c) of Medical Devices Act No. 123/2000, Collection of Laws, as amended);
Pursuant to Section 2, Subsection 2 of the GO 453 this Government Order shall also apply to

- o in vitro diagnostic medical devices manufactured and intended to be used for analyses in clinical laboratories even if not being subject of business
- o mechanical laboratory devices designed specifically for in vitro diagnostic examination
- o in vitro diagnostic medical devices manufactured from tissues, cells or substances derived from the human body
- o accessories of in vitro diagnostic medical devices handled as separate in vitro diagnostic devices
- o in vitro diagnostic medical devices which are calibrators or control materials needed to determine or verify performance capability by their user.

Pursuant to Section 2, Subsection of the GO 453 this Government Order does not apply to:

- o tools, instruments, devices or other objects including software intended to be used for research purposes without any medical objective
- o internationally certified reference materials and materials used for programmes of external quality system assessment
- o agents manufactured in laboratories of a health care facility to be used in the environment of these laboratories and are not a subject of business
- o medical devices for an invasive human body sampling
- o in vitro diagnostic medical devices manufactured in a health care facility and used only in this health care facility without being given to other user
- o other medical devices manufactured while using substances derived from the human body (with the exception of the in vitro diagnostic medical devices manufactured from tissues, cell or substances derived from the human body.

- **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 EU Directive and Government Order;

- **essential requirements** mean 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 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 appropriate essential requirements of the EU Directives and the Government Orders 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 /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 Government Order 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 authorised to conduct its activities;

- **manufacturer** means a person who designs, manufactures, packs and labels a medical device and is responsible for the above activities before the device is placed on the market under his own name and surname, firm or name regardless of whether these operations are carried out by that person himself or on his behalf by a third party authorised in writing by the manufacturer to act on his behalf with respect to requirements arising for the manufacturer from the Medical Devices Act No. 123/2000, Collection of Laws, as amended.

- **authorised representative** means a person established in a member state of EU who is **authorised** in writing by the manufacturer to act on his behalf with respect to meeting requirements of appropriate directives (and implementation thereof into national legislations of the member states) placed on the manufacturer;

- **placing on the market** means the first making available in return for payment or free of charge of an in vitro diagnostic medical device other than a device intended for performance evaluation with a view to distribution and/or use on the Community market, regardless of whether it is new or fully refurbished;

### *2.2. Abbreviations used*

| | |
|---|---|
| ATL | Accredited testing laboratory |
| Directive | For the purposes of this Manual New Approach Directive, which lays down technical requirements for a given product area |
| ITC | Institut pro testování a certifikaci, a.s. (Institute for Testing and Certification, a.s.) |
| NB | notified body |
| NB 1023 | Notified Body 1023 (this designation has been assigned to ITC by the European Commission) |
| GO | Government Order |
| GO 453 | Czech Republic's Government Order No. 453/2004, Collection of Laws, setting out technical requirements for in vitro diagnostic medical devices. |
| OSMT | Office for Standards, Metrology and Testing |
| Act 22 | Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing certain laws, as amended |
| IVD | In vitro diagnostic medical device |

## 3. Scope of ITC's notification

ITC's notification in the area of the Council Directive 98/79/EC and GO 453 covers all IVDs and conformity assessment procedures pursuant to Section 8 of the GO 453. The scope of the notification has been set out by the OSMT's Decision.

## 4. Legal regulations

### *4.1. Act 22/1997, Collection of Laws, and GO 453/2004, Collection of Laws*

The legal 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. In vitro diagnostic medical devices are specified products in the sense of Section 12, Subsection 1 of the Act 22. Technical requirements for medical devices are contained at a general level in Act 123/2000, Collection of Laws, as amended, and made specific for IVDs in Czech Republic's Government Order 453, which implements requirements of the Directive 98/79/EC as amended, into the Czech legal regulations.

### *4.2. Related regulations*

In this part related legal regulations for customer's information are given that must be taken into account in the process of conformity assessment of products placed on the markets of EU and the Czech Republic. It includes notably the Public Health Protection Act and its implementing decrees and acts on liability for damage caused by a defective product:

- Act 123/2000, Collection of Laws, on medical devices and on an amendment of some related acts
- Act 130/2003, Collection of Laws, which amends the Act 123/2000, Collection of Laws, on medical devices and on an amendment of some related acts, and some other acts
- Act 346/2003, Collection of Laws, by which a full text is promulgated of the Act 123/2000, Collection of Laws, on medical devices and on an amendment of some related acts as follows from amendments implemented by Act 130/2003, Collection of Laws, and Act 274/2003, Collection of Laws,
- Act 58/2005, Collection of Laws, by which the Act 123/2000, Collection of Laws, on medical devices and on an amendment of some related acts, as amended, and on Trade Licenses (Trade Licensing Act), as amended
- Act 59/1998, Collection of Laws, on liability for damage caused by a defective product, as amended
- Act 102/2001, Collection of Laws, on general safety of products and on an amendment of some acts, as amended
- Ministry of Health's Decree 501/2000, Collection of Laws, which defines forms, ways of reporting undesirable events of medical devices including forms and ways of registering, investigating, assessing and documenting such events, storing the documentation and subsequent monitoring such devices with the aim of preventing occurrence of undesirable events, particularly their reoccurrence (Decree on undesirable events of medical devices)
- Ministry of Health's Decree 304/2003, Collection of Laws, which amends the Decree 501/2000, Collection of Laws, on undesirable events of medical devices
- Act 258/2000, Collection of Laws, on Public Health Protection and an amendment of some related acts, as amended

## 5. Harmonized technical standards related to conformity assessment of in vitro diagnostic medical devices

If an IVD is in conformity with harmonized standards related thereto with respect to the specified purpose of use, then it meets essential requirements of Annex 1 of the GO 453. A survey of harmonized standards for in vitro diagnostic medical devices is available on web pages of the Czech Standardization Institute.
http://domino.cni.cz/NP/NotesPortalCNI.nsf/key/produkty_a_sluzby~normy~harmonizovane_normy?Open

## 6. Conformity assessment of in vitro diagnostic medical devices

### *6.1 General principles*

Every in vitro diagnostic medical device must meet essential requirements set out in Annex 1 to GO 435 related to this device with respect to its defined purpose of use. Meeting the essential requirements is the basic prerequisite of conformity assessment.
The essential requirements set out in Annex 1 to the GO 453 are given briefly in the points shown below:

General requirements

- The in vitro diagnostic medical devices must be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition, the safety or health of users or, where applicable, the safety of property.
- The solutions adopted by the manufacturer for the design of the IVDs must be based on the current state of the art while conforming to principles of safe design and development, taking measures against risks that cannot be eliminated and informing users of the residual risks due to any shortcomings of the protection measures adopted.
- The IVDs must be designed and manufactured in such a way that they are suitable for the purposes referred to in the Medical Devices Act, as specified by the manufacturer, and capable of achieving the performances, in particular, where appropriate, in terms of analytical sensitivity, diagnostic sensitivity, analytical specificity, diagnostic specificity, accuracy, repeatability, reproducibility, including control of known relevant interference, and limits of detection, stated by the manufacturer.
- The characteristics and performances must not be adversely affected to such a degree that the health or the safety of the user are compromised during the usable life or lifetime of the IVD as indicated by the manufacturer, not even when the device is subjected to the stresses which can occur during normal conditions of use.
- The devices must be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected under storage and transport conditions taking account of the instructions and information provided by the manufacturer.

Design and manufacturing requirements

- chemical, physical and biological properties
- infection and microbial contamination

- manufacturing and environmental properties of the in vitro diagnostic medical devices
- in vitro diagnostic devices as instruments or apparatus with a measuring function
- protection against radiation
- requirements for in vitro diagnostic medical devices connected to or equipped with an energy source
- requirements for in vitro diagnostic medical devices for self-testing
- information supplied by the manufacturer.

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

### *6.2 Inclusion of in vitro diagnostic medical devices into lists*

In compliance with the Annex II of the Directive 98/79/EU (Annex 2 to the GO 453) IVDs are included in lists „A“ and „B“, in vitro diagnostic medical devices for self-testing are included in list „C“ while the others in list „D“.

### *6.3 Procedures for conformity assessment of in vitro diagnostic medical devices*

All medical devices referred to in Subsection 6.2 of the present Manual, with the exception of in vitro diagnostic medical devices falling within list „D“, are subject to conformity assessment with the participation of a notified body. Procedures for conformity assessment of IVDs are specified in Section 8 of the GO 453. Procedures according to Annexes 3 to 8 to the GO 453 are used in the conformity assessment. The Annexes are characterized briefly in the subsections as follows. In order to verify whether essential requirements laid down in the Annex I to GO 453 for IVDs referred to in the lists „A“ and „B“ have been met common technical specifications contained in Annex X to GO 453 *(Decision of European Commission of 7 May 2002 on common technical specifications for in vitro diagnostic medical devices)* which establishes criteria for performance evaluation and re-evaluation of IVD, batch release criteria, reference methods and reference materials.

#### *6.3.1 Annex 3 – EC declaration of conformity*

In compliance with Section 6 of this Annex the manufacturer shall lodge an application for examination of the design with a notified body for in vitro diagnostic medical devices for self-testing (referred to in the list „C“). The notified body proceeds pursuant to subsection 6.2 and issues the applicant with an EC design-examination certificate provided the design conforms to the relevant provisions of the GO 453. The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the design-related requirements of the GO 453.

The manufacturer shall use this Annex to assess conformity of the IVDs referred to in the lists „C“ and „D“ pursuant to Section 2-5.

#### *6.3.2 Annex 4 – EC declaration of conformity (Full quality assurance system)*

The most comprehensive conformity assessment procedure. Using this procedure the manufacturer ensures application of the quality system approved for the design, manufacture and final inspection of the in vitro diagnostic medical devices concerned, as specified in Section 3 of this Annex. When using the conformity

assessment procedure according to Annex 4 the notified body conducts an audit at the manufacturer's premises as laid down in Section 3.3, to find out whether the quality system meets the requirements set out in Section 3.2 of this Annex. According to Section 5 of this Annex the manufacturer is also subject to a surveillance performed by the notified body, the aim of which is to ascertain if the obligations arising from the approved quality system are dully fulfilled. The manufacturer can proceed according to harmonized standards ČSN EN ISO 9001: 2001 or ČSN EN ISO 13485: 2003.
In the case of in vitro diagnostic medical devices covered by Annex II, List „A“ the devices are assessed also in compliance with Section 4, according to which the notified body will assess design of the in vitro diagnostic medical device.

In the case of in vitro diagnostic medical devices covered by List „A“, the manufacturer shall carry out the required controls and tests according to the latest state of the art and after the conclusion of the controls and tests, he shall forward to the notified body the relevant reports on the tests carried out on the manufactured devices or each batch of devices without delay. Furthermore, the manufacturer shall make the representative samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions. The manufacturer may place the devices on the market under conditions laid down in Subsection 6.2. of this annex.

### *6.3.3 Addendum 5 – EC type examination*

EC type examination of an in vitro diagnostic medical device is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered (hereinafter referred to as only „type“) fulfils the relevant provisions of this Directive related thereto. In this connection the manufacturer guarantees and declares that the in vitro diagnostic medical devices delivered to the market conform to the certified type.
The manufacturer or his **authorised** representative will request NB for type examination pursuant to Section 2 of this Annex and supply documentation which must enable to understand the design, manufacture and performance of the in vitro diagnostic medical device, as set out in Section 4 of this Annex.

### *6.3.4 Annex 6 – EC verification*

EC verification is the procedure whereby the manufacturer or his authorised representative ensures and declares that the in vitro diagnostic medical devices which have been subject to the examination set out in Section 4 of this Annex conform to the type described in the EC type-examination certificate. During this procedure the notified body will verify and review conformity of the in vitro diagnostic medical device with requirements of this Order either on each product (Section 5) or on the basis of a statistical (random) sample taken from homogeneous batches (Section 6). The notified body then releases separate products or batches and draws up a Certificate of Conformity relating to the tests carried out.

### *6.3.5 Annex 7 – EC Declaration of Conformity (Production quality assurance)*

The declaration of conformity – production quality assurance is the part of the procedure whereby the manufacturer ensures implementation of the quality system approved for the manufacture of the given IVDs, performs outgoing (final) inspection

of the medical device and declares that the IVDs concerned conform to the type described in the EC type-examination certificate and meet the provisions which apply to them. During the conformity assessment according to Annex 7 the notified body conducts at the manufacturer's premises an audit referred to in Section 3.3 of the Annex whereby it ascertains whether the quality system conforms to the requirements specified in Section 3.2 of the Annex. According to Section 4 of this Annex the manufacturer is also subject to a surveillance performed by the authorised body, which thus ascertains if the obligations arising from the approved quality system are dully fulfilled.

### *6.3.6 Annex 8 – EC Declaration of Conformity and procedures concerning in vitro diagnostic medical devices for performance evaluation*

When proceeding in compliance with this Annex the manufacturer or his authorised representative shall draw up, for performance evaluation of in vitro diagnostic medical devices, a statement containing the information stipulated in Section 2 of this Annex and ensure that the relevant provisions of this Order are met.

(This provision does not affect regulations relating to the ethical aspects of carrying out performance evaluation studies using tissues or substances of human origin contained in the Helsinki Declaration adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, as amended).

## 7. Selection of conformity assessment procedure

The choice of a conformity assessment procedure depends on inclusion of the in vitro diagnostic medical device into separate Lists („A“, „B“, „C“ and „D“). The following table gives procedures that can be used in assessing conformity of IVDs in separate Lists. From the table it is apparent that even in case of IVDs covered by the same List there are more alternatives for selection of a conformity assessment procedure. 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 inclusion of the given in vitro diagnostics in separate Lists**

| Annex to GO 453 | Manufacturer's activity | Notified Body's activity<br>*Document issued* |
|---|---|---|
| **in vitro diagnostic medical devices for self-testing (List „C“)** | | |
| **3 (Section 6)** | preparation of technical documentation according to Section 3 of Annex 3 and ensuring conformity with requirements of this Annex | design review according to Section 6 of Annex 3<br>***EC Design review certificate*** |
| **4 (except for Section 4)** | preparation of technical documentation according to Subsection 3.2 of Annex 4 and ensuring conformity with requirements of this Annex | assessment of full quality system by an audit at the manufacturer's premises according to Annex 4 (except for design review according to Section 4)<br>***EC Certificate***<br><br>surveillance according to Section 5 of Annex 2<br>***Assessment Report*** |
| **5 plus 6** | preparation of technical documentation according to Section 3 of Annex 5 and ensuring conformity with requirements of Annexes 5 and 6 | examination of type according to Annex 5<br>***EC type examination certificate***<br><br>conformity verification of each piece manufactured, with the verification being done according to Section 5, or of a statistically selected sample according to Section 6 of Annex 6<br><br>***EC Certificate of conformity of each IVD***<br>***EC Certificate of conformity of batch (lot)*** |
| **5 plus 7** | preparation of technical documentation according to Section 3 of Annex 5 and Subsection 3.2 of Annex 7 and ensuring conformity with requirements of Annexes 5 and 7 | examination of type according to Annex 5<br>***EC type examination certificate***<br><br>assessment of production quality system according to Annex 7 (by an audit of the manufacturer's production facility)<br>***EC Certificate***<br><br>surveillance according to Section 4 of Annex 7 (Section 5 of Annex 4)<br>***Assessment Report*** |
| **in vitro diagnostic medical devices covered by Annex 2, List „B“** | | |
| **4 (except for 4)** | preparation of technical documentation according to Subsection 3.2 of Annex 4 and ensuring conformity with requirements of this Annex | assessment of full quality system by an audit at the manufacturer's premises according to Annex 4 (except for design review according to Section 4)<br>***EC Certificate***<br><br>surveillance according to Section 5 of Annex 4<br>***Assessment Report*** |

| Annex to GO 453 | Manufacturer's activity | Notified Body's activity<br>*Document issued* |
|---|---|---|
| **5 plus 6** | preparation of technical documentation according to Section 3 of Annex 5 and ensuring conformity with requirements of Annexes 5 and 6 | examination of type according to Annex 5<br>***EC type examination certificate***<br><br>conformity verification according to Section 5 on each piece manufactured or according to Section 6 of Annex 6 on a statistically selected sample<br>***EC Certificate of conformity of each IVD***<br>***EC Certificate of conformity of batch (lot)*** |
| **5 plus 7** | preparation of technical documentation according to Section 3 of Annex 5 and Subsection 3.2 of Annex 7 and ensuring conformity with requirements of Annexes 5 and 7 | examination of type according to Annex 5<br>***EC type examination certificate***<br><br>assessment of production quality system according to Annex 7 (by an audit of the manufacturer's production facility)<br>***EC Certificate***<br><br>surveillance according to Section 4 of Annex 7 (Section 5 of Annex 4)<br>***Assessment Report*** |
| **in vitro diagnostic medical devices covered by Annex 2, List „A“** | | |
| **4 (including Section 4)** | preparation of technical documentation according to Subsection 3.2 of Annex 4, description of design according to Subsection 4.2 and ensuring conformity with requirements of this Annex | design review according to Section 4 of Annex 4<br>***EC Design review certificate***<br><br>assessment of full quality system according to Annex 4 (by an audit at the manufacturer's premises)<br>***EC Certificate***<br><br>verification according to Annex 4, Section 6<br>surveillance according to Annex 4, Section 5<br>***Assessment Report*** |
| **5 plus 7** | preparation of technical documentation according to Annex 5, Section 3, and Annex 7, Subsection 3.2, and ensuring conformity with requirements of Annexes 5 and 7 | examination of type according to Annex 5<br>***EC type examination certificate***<br><br>assessment of production quality system according to Annex 7 (by an audit of the manufacturer's production facility)<br>***EC Certificate***<br><br>verification according to Annex 7, Section 5<br>surveillance according to Annex 7, Section 4 (Annex 4, Section 5)<br>***Assessment Report*** |

# 8 Notified Body's procedures for conformity assessment of an in vitro diagnostic medical device

This section describes steps that the manufacturer or his authorized representative must take in assessing conformity of the 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 a 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 (Centre for Certification of Medical Devices)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
CZ-764 21 Zlín, Czech Republic
tel. (+420) 577 601 357, fax. (+420) 577 104 855, e-mail: vkahanek@itczlin.cz

b) MUDr. Beata Janoušková (an expert for conformity assessment of IVDs in compliance with GO 453)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
CZ-764 21 Zlín, Czech Republic
tel. (+420) 577 601 276, fax. (+420) 577 104 387, e-mail: mikrobiologie@itczlin.cz

c) Jitka Fusková (secretariat of the Certification Division)
Institut pro testování a certifikaci, a.s.
třída Tomáše Bati 299
CZ-764 21 Zlín, Czech Republic
tel. (+420) 577 601 623, fax. (+420) 577 104 855, e-mail: jfuskova@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 VSTUP > Notifikovaná osoba > In vitro diagnostika > Žádost /ENTRY > Notified Body > In vitro Diagnostic Medical devices > Application/) or at the request addressed to any of 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 advisable to supply, together with the application, also **documentation** as required by the GO 453. **The table in Annex 2 of the present Manual giving a list of recommended 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 5 or 6, it is suitable, on agreement with an expert, to supply also samples of the in vitro diagnostic medical device to be assessed.

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

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

8.1.4. Neither the Directive 98/79/EC nor the Act 22 make possible for the manufacturer or his authorized representative to lodge the application for conformity assessment of the same in vitro diagnostic 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 review at this stage correctness and completeness of the data given in the application, 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. According to inclusion of the in vitro diagnostic medical device in the List and selected method of conformity assessment it will determine whether an audit at the manufacturer's premises is needed (see Table 1 of this Manual), 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 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 applicant's behalf. Should the price of the contract exceed CZK 10000 the NB will send the applicant simultaneously with the contract also an invoice for payment of an advance, 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. Should the applicant's comments be unacceptable and personal negotiation not successful the contract will not be concluded and NB 1023 secretariat will notify the applicant thereof in writing.*

*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 GO 453 includes the procedure according one of the **Annexes 5 or 6,** it is suitable for the client to deliver a sample of the IVD together with the application. Since the testing of the IVD itself depends very much on the type and character of the IVD, it is suitable to consult sampling with the expert in advance. When agreed, the IVD 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 written or telephone instructions provided by the responsible worker of NB 1023 at the client's request. 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 98/42/EC and GO 453 are given.

### *8.5. Conformity assessment process itself*

*8.5.1. If the Section 8.3.1 stipulated that an audit must 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 will assure appropriate assessments and necessary tests of the IVD samples in its own laboratories or in contractual accredited or national reference laboratories approved by ÚNMZ.*

*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 IVD, 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 IVD with requirements of the Directive 98/79/EC and GO 453.*

*8.5.5. If the conclusions are positive, NB 1023 will draw up a Certificate (see the survey of the certificates issued by the NB 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. 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 IVD fails to meet the requirements related thereto with respect to its intended purpose, 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 and performance of the IVD 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 relevant validated test methods the implementation of which would be difficult at AZL, may constitute an exception.*

### *8.7. Validity of Certificates drawn up by NB*

8.7.1. Geographical validity of the certificates is given by the number of countries that implemented the Directive 98/79/EC into their legal system and allow placement of CE-marked products on their own markets. They are primarily member states of EU and ESVO.

8.7.2. In compliance with the provision of Section 8, Subsection 10 of the GO 453 the certificates and documents issued by NB 1023 (ITC) expire after 5 years at the latest but can be extended by another 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, manufacturing process of the IVD be made, the usual interval between the inspections is 1 year.

## 9. Surveillance of conformity assessed in vitro diagnostic medical devices

*9.1. If the conformity assessment was carried out successfully the NB conducts a regular surveillance at the manufacturer's 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 to 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 NB 1023 (ITC).*

9.2. If the technological conditions of the manufacture and materials used are changed or the intended use (performance) of the in vitro diagnostic medical device for which the Certificate has been issued is modified the manufacturer is obliged to notify NB 1023 (ITC) of this fact in writing.

*9.3. Thereafter, NB 1023 will consider whether the announced changes can lead to changes of safety and performance parameters of the IVD and to changes in meeting the essential requirements of GO 453, Annex 1, and inform in writing the certificate holder whether or not a new conformity assessment is necessary.*

*9.4. NB 1023 personnel will notify in writing the certificate holder of a change in the legal regulations 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 operation as soon as he fulfils the obligations imposed on him by requirements of the GO 453, Section 5, Subsection 1. The IVD may be introduced to the market and put into operation if

- conformity assessment was carried out in the specified manner in compliance with Section 8;
- it meets the essential requirements and further provisions of GO 453 related thereto;
- the manufacturer or his authorized representative has made a written declaration (Declaration of Conformity) pursuant to GO 453;
- the IVD is provided 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 EU 93/68/EEC. The CE marking must be made in a visible, easily legible and indelible form on the medical device or its pack;
- information on its use has been attached to the IVD (in the Czech Republic the information on its use must be in the Czech language).

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 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 in vitro diagnostic medical device with the requirements of GO 453 must be available. The manufacturer shall store the documentation for at least 5 years following manufacture of the last in vitro diagnostic medical device 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:

- assessment of documentation to the in vitro diagnostic medical device covered by List „D“ in case of which the participation of NB in conformity assessment pursuant to requirements of GO 453, Annexes 1 and 3 is not necessary. The documentation assessment is completed with elaboration of a “Final Report on Documentation Assessment”;
- certification and attestation of in vitro diagnostic medical devices covered by List „D“ by the Accredited Certification Body 3020;
- 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 GO 453;
- in products featuring a high quality level, certification and issue of a licence on affixing ITC quality marking (Certifikovaná kvalita / 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 Division 3 (telephone 577 601 623).

## 12. Conclusion

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

# ANNEX No. 1

## Application form for conformity assessment of a medical device by Notified Body NB 1023

## Institute for testing and certification, a.s., Zlín

**INSTITUTE FOR TESTING AND CERTIFICATION, a. s.**

**Quality system certified according to ČSN EN ISO 9001:2001**

Notified Body 1023 * Authorized Body 224

# APPLICATION FOR CONFORMITY ASSESSMENT OF AN IN VITRO DIAGNOSTIC MEDICAL DEVICE

**pursuant to Directive 98/79/EU, Section 9, and Government Order 453/2004, Collection of Laws, as amended**

**No** | | | | | | | | | |

ITC' registry number (do not fill in)

## APPLICANT:

| | | |
|---|---|---|
| **Company name:** | VAT No. | |
| | Registration No.: | |
| | Registered at: | |
| Address: | Phone: | |
| | Fax: | |
| Post Code | E-mail: | @ |
| Banking with: | Account No.: | |
| Statutory representative: | | |
| Person authorized to conduct negotiations: | | |

## PRODUCT:

| |
|---|
| **Name:** |
| **Type** (give more detailed specifications on page 2 of this Application): |
| Company name and manufacturer's address (if different from that of the applicant): |
| The manufacturer is a part of a bigger economic unit (if so, give the name of the unit): ☐ yes ☐ no |

## SPECIFICATION OF CONFORMITY ASSESSMENT PROCEDURE:

| | |
|---|---|
| Specified conformity assessment procedure pursuant to GO 453/2004, Collection of Laws:<br><br>(check the relevant item) | ☐ Annex 3, Section 6 - Review of design of IVD for self-testing<br>☐ Annex 4 - Full quality assurance system<br>☐ Annexes 5+6 - Type examination + verification<br>☐ Annexes 5+7 - Type examination + Production quality assurance<br>☐ Other requirement (specify): |
| The applicant is interested in a consultation on the conformity assessment procedure: | ☐ yes ☐ no |
| Required foreign language versions of the documents issued: | ☐ Czech ☐ English ☐ other ( ) |

**Applicant's statement:**

1. *We agree that the product samples will not be returned after tests.*
   *The application for conformity assessment of this product has not been lodged with any other notified body.*

.....

Date of application lodging

.....

Stamp and signature of applicant's authorized representative

# Detailed specification of the type of the in vitro diagnostic medical device (IVD) submitted for the conformity assessment

## ACCOMPANYING DOCUMENTATION:

| | | |
|---|---|---|
| Name and description of the product: | | |
| A list of the parts attached to the technical documentation according to specification in Annexes to GO 453/2005, Collection of Laws (illustrations, schemas, catalogue sheet, instructions for use and assembly, technical conditions and other information characterizing the product): | | |
| The product in question is an IVD medical device for self-testing: | ☐ yes | ☐ no |
| The product in question is an IVD for performance verification: | ☐ yes | ☐ no |
| Intended purpose of the product: | | |
| Has the product been placed on the market?<br>If the product has been placed on the market, state when:<br>If the product has been placed on the market, state in what countries: | ☐ yes<br>In the year | ☐ no |
| Is the product designed and manufactured in a documented quality control system?<br>If so, indicate the standard or other specification of the system: | ☐ yes | ☐ no |
| Has the implemented quality control system been certified? | ☐ yes | ☐ no |
| Are reports by accredited testing laboratories available?<br>If so, give a list of the reports (report numbers): | ☐ yes | ☐ no |
| A list of documents related to the quality control system (certificates, records of certification and surveillance audits, etc.) | | |
| Further documents, data and information: | | |

# ANNEX 2

# Methodical aid containing recommended range of documentation

## for conformity assessment of IVD by Notified Body NB 1023

## Institute for testing and certification, a.s., Zlín

# Methodical aid

for assembly of documentation to application for conformity assessment of an in vitro diagnostic medical device
pursuant to GO 453/2004, Collection of Laws, implementing Directive 98/79/EC into the Czech legal regulations

| **Documentation** | |
|---|---|
| IVD name, type/model | |
| Included in the category (Annex 2, List A, List B, IVD for self-testing) | |
| A brief description of the IVD<br>* a list of reagents contained in the set | |
| Intended purpose | |
| For products in a sterile state, a description of the sterilization method and its validation | |
| Risk analysis | |
| Technical documentation necessary for meeting the essential requirements for IVD in compliance with Annex I (checklist) | |
| * General requirements | |
| * Chemical, physical and biological properties | |
| * Infection and microbial contamination (including packaging systems) | |
| * Environment related requirements for design and properties | |
| | |
| *For IVD which are an instrument with a measuring function* | |
| * *Stability and precision of the measuring functions* | |
| * *Ionizing radiation (effect, level control, protection…)* | |
| * *Electric and electromagnetic properties* | |
| * *Reliability, efficiency and operating stability of software* | |
| * Usability – life (stability study) | |
| * *For self-testing IVD – results of studies conducted by lay users* | |
| Information provided by manufacturer (Czech user instruction leaflets, instructions, instructions for use, marking) | |
| Appropriate tests of the IVD, test results, test reports, certificates, analyses, standards used | |
| Documentation to product design (if relevant) | |
| *Documentation to type certificate (if relevant)* | |
| Information that manufacture of the IVD meets requirements of the quality system according to: | |
| | |
| * EN ISO 9001:2000 | |
| * EN ISO 13485 : 2003<br>* other | |
| Documents from certification audits, surveillance audits, non-compliance notes (non-conformity records) | |
| Documents showing manufacturer's and importer's guarantee on acquiring information and experience of IVD users, on implementing a system of reporting and recording undesirable events (Laws 123/2000 as amended by Law 130/2003, Collection of Laws, Decree 501/2000, Collection of Laws, as amended by Decree 304/2003, Collection of Laws | |
| Results of performance tests, evaluations, studies | |

# ANNEX 3

## A sample contract for conformity assessment

### pursuant to Section 8 of GO 453/2004, Collection of Laws, by Notified Body NB 1023

## Institute for Testing and Certification, a.s., Zlín

# CONFORMITY ASSESSMENT CONTRACT NO. XXXXXXX

concluded pursuant to provisions of Sections 10, 12 et seq. of Law 22/1997, Collection of Laws, on technical requirements for products, as amended, and in compliance with provisions of Sections 591-600 of Law 513/1991, Collection of Laws (Commercial Code), as amended

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Article I
**Parties to the Contract**

1. Company name:
   having its seat at:
   represented:
   banking with:
   having Company registration number: Company Tax Registration Number:
   registered at the Regional Court:
   as a manufacturer, authorized representative or distributor of the product assessed (hereinafter referred to as only Client)
   Person authorized to conduct negotiations in matters related to the Contract:

2. **Institut pro testování a certifikaci, a. s.**
   having its seat at: tř. T. Bati 299, 764 21 Zlín, Czech Republic
   represented by: RNDr. Radomír Čevelík, Director General
   person authorized to sign the Contract and negotiate its content: Dipl. Ing. Pavel Vaněk, Director of Certification Division
   banking with: KB, a. s., Prague, branch at Zlín, bank account number: 12903-661/0100
   having IČ (Company registration number): 47910381 and
   DIČ (Company Tax Registration Number): CZ47910381
   registered at the Regional Court in Brno, Rider B/1002
   which is an **Authorized Body AO 224** and **Notified Body No. 1023** operating within European Union pursuant to Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing some laws, as amended (hereinafter referred to as only **Assessor**).

Article II
**Subject-matter of the Contract**

1. Based on the Client's request registered under number XXXXXX dated DD.MM.YYYY the Assessor undertakes to carry out, in an impartial manner, works aimed at certifying conformity of a product and activities with manufacture related to technical requirements for products, namely for

   **XXXXXXXXXXXXXXXXXX**

   using procedures documented by Law 22/1997, Collection of Laws, as amended, and assessment of conformity of products according to Government Order 453/2004, Collection of Laws, which lays down technical requirements for in vitro diagnostic medical devices, and which contains requirements specified by Directive 98/79/EC.

2. The Client undertakes to provide a cooperation necessary for conducting certification, to take measures at his organisation that are necessary for granting the certificate and to pay for the work done a price indicated in Article IV of the present Contract in a manner set forth in the same article.

Article III
**Period of execution of the contract**

1. The Assessor undertakes to carry out the conformity assessment activities in compliance with Article II, paragraph 1 within 2 (two) months from the start of the works.

2. The start of the conformity assessment works by the Assessor shall be subject to signing the present Contract, paying an advance pursuant to Article IV, paragraph 2 of the present Contract,

presenting prescribed technical documentation and/or product samples. Day of start of the works shall be the day following the moment all agreed terms and conditions have been met.

3. The Assessor reserves the right to perform the Contract ahead of the date agreed in this Contract. The Assessor's obligation under this Contract shall be deemed fulfilled by delivering Final Report and Certificate to the Client by registered mail. In the event the above documents have been supplied and received by the parties to the Contract personally the Client is obliged to confirm the receipt of the conformity assessment results in writing.

Article IV
**Price and payment terms**

1. In compliance with provision of Section 12, Subsection 5 of Act 22/1997, Collection of Laws, on technical requirements for products and on amending and complementing some laws, as amended, and pursuant to Act 526/1990, Collecton of Laws, on prices, as amended, the parties to the Contract have agreed on price for providing the service under the present Contract amounting to

CZ XXXXXX
say: XXXXXXXXXXXXX

A value added tax (VAT) in compliance with the legislation currently in force in the Czech Republic shall be added to the above price.

The price does not include costs of transport and accommodation. The price of the order shall be increased by the amount of these costs. The increase in price of the order shall be documented by documents showing real expenses.

2. The Client undertakes to pay the Assessor an advance amounting to the entire sum of money agreed. In case of payment of an advance (an advance payment) the amount will be taxed in compliance with Czech Republic's legislation.

When the works under the present Contract have been completed, the Assessor shall issue a final invoice, in which the advance payment will be deducted and the invoice shall be sent to the Client together with the documents specified in Article III, paragraph 3 of the present Contract.

3. Non-cash payments shall be effected by order to transfer the money to Assessor's account. The Client's oblidation to pay an advance shall be fulfilled when the amount to be paid has been added to the Assessor's account at his bank. In case of cash payment this obligation shall be fulfilled by payment of the agreed amount at Assessor's cash office.

4. To pay the advance the Client shall use the number of the present Contract as a variable symbol.

Article V
**Infringement of contractual obligations and its consequences**

1. In the event of an Assessor's delay in execution of the works according to Article II of the present Contract the Assessor shall be obliged to pay a contractual fine amounting to 0.02% of the price of the Contract for each day of the delay.

2. Should the Client be in default in payment of the final invoices pursuant to Article IV of the present Contract the Client shall be obliged to pay a late payment charge amounting to 0.02% of the price of the Contract for each day of the default.

Article VI
**Withdrawal from the Contract**

1. Should the Client fail to pay the advance pursuant to Article IV, paragraph 2 of the present Contract within 21 days **from conclusion of the Contract**, the Client shall be deemed to have withdrawn from the Contract and the Contract shall be cancelled without a claim to a compensation.

Article VII
**Further agreements**

1. Both parties to the Contract undertake to keep the confidentiality rules concerning all facts related to performance of the Contract.

2. The present Contract shall not affect legal relationship between the Client and third persons, particularly those persons for whom the product assessed is intended or from whom the product originates. It means that the Contract covers neither Client's legal relationships in case of an appeal against the Assessor's decision on his decision to refuse carrying out conformity assessment, nor legal relationships in conducting a surveillance audit of the product assessed.

3. The parties to the Contract have hereby agreed to conclude a contract concerning performance of a surveillance (inspection activity) of the assessed product if the outcome of the conformity assessment is positive. The precise extent of the surveillance shall depend on findings of the conformity assessment carried out pursuant to the present Contract and shall be set out by the final report No. XXXXXXXXX. The surveillance (inspection) contract pursuant to Section 12 of Act 22/1997, Collection of Laws, as amended, (random or regular inspections) will be concluded at the Authorized Body's request not later than 6 (six) months from the date on which the results of the conformity assessment were provided to the Client. Such a Contract shall contain particularly information on extent, price and date of the surveillance. The costs of this activity shall be covered by the Client in compliance with the provision of Section 12, Subsection 5 of Act 22/1997, Collection of Laws, as amended.

4. The person performing the surveillance (inspection) reserves the right to conduct justified extraordinary surveillance audits based on incentives (complaints, claims, changes in manufacture, technical specification amendments, etc.) at the Client's costs (see Section 12, Subsection 4, letter č), paragraph 5 of Act 22/1997, Collection of Laws, as amended.

5. The Client agrees that services of accredited laboratories may be used in tests.

6. The Client is obliged to send to Assessor's address records of tests, copies of release reports or, if relevant, product samples from manufacture of each in vitro diagnostic medical device covered by list A, Annex 2 to GO 453/2004, Collection of Laws, prior to its placement on the market.

7. The Assessor shall assess the documentation pursuant to paragraph 5 of this Article and in case of conformity with the requirements he shall give his written consent to placement of the product batch on the market without delay. In the event of non-conformity he shall not give his consent thereto. Costs of the tests of the batches and assessment of their conformity with the requirements shall be borne by the manufacturer.

Article VIII
**Common and final provisions**

1. Matters not covered by the present Contract and legal relations arising from this Contract shall be governed particularly by Act 22/1997, Collection of Laws, as amended, by related regulations and the general regulations contained in the Commercial Code.

2. Any changes, amendments and modifications of the present Contract snall not be valid unless made in written addenda consented to by the parties to the Contract.

3. The Client declares that the Contract is being signed by a person authorized to act on his behalf and that the data concerning his company are up-to-date and correct. Otherwise he undertakes to cover costs incurred by giving faulty data.

4. The present Contract is being made in duplicate. Each party to the Contract will receive one copy having validity of original.

5. The Contract becomes effective on the date of its signing by the Client. The draft of the Contract signed by the Assessor shall be valid for **2 (two) months**. Should the Client fail to sign and deliver the Contract within this period of time the Contract shall be deemed not to have been concluded.

6. The parties to the Contract are declaring that the Contract is an expression of their true and free will, that it is being concluded neither in a distress nor in conditions disadvantageous for any of the parties hereto. In witness whereof, the parties hereto have executed this Contract.

Done in …….. on…….. Done in Zlín on DD.MM.YYYY

For Client: For Assessor: