**APPLICATION FOR CONFORMITY ASSESSMENT**

**OF** **IN VITRO DIAGNOSTIC MEDICAL DEVICES**

according to the Article No. 9 of the Directive 98/79/EC (IVD) as amended

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **No.:** |  |  |  |  |  |  |  |  |  |

ITC’s Registry Number (do not fill in)

**MANUFACTURER:**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Company name:** | | | | | | | | | | VAT No.: |  |  |  |  |  |  |  |  |  |  |
|  | | | | | | | | | | Id. No.: | | |  |  |  |  |  |  |  |  |
| Address: | | | | | | | | | | Phone: | | |  | | | | | | | |
|  | | | | | | | | | | Fax: | | |  | | | | | | | |
| Zip Code: |  |  | **-** |  |  |  |  |  |  | e-mail: | | | @ | | | | | | | |
| Banking with: | |  | | | | | | | | Account No.: | | |  | | | | | | | |
| IBAN code: | |  | | | | | | | | SWIFT code: | | |  | | | | | | | |
| Manufacturer’s unique code in the database Eudamed, if granted (see page 3): | | | | | | | | | | | | |  | | | | | | | |
| Manufacturer’s code in the Czech Ministry of Health register, if granted (see page 3) : | | | | | | | | | | | | |  | | | | | | | |
| Represented by: | | | | | | | | | | | | | | | | | | | | |
| Person authorized to negotiation: | | | | | | | | | | | | | | | | | | | | |

**IVD Medical Device:**

|  |
| --- |
| **Brand Name** under which the IVD shall be placed on the market – this brand name shall appear on the certificate**:** |
| **Type(s)/Model(s) covered by the Application** – please write the more detailed specifications on the page 2: |
| **IVD Device Category:**  IVD for self-testing  List B  List A |
| Is your company part of some larger organisation? (if yes, specify its name):  yes  no |

**conformity assessment procedure:**

|  |  |
| --- | --- |
| The chosen conformity assessment procedure | Annex III, point 6 EC Design Examination (self-testing IVD) |
| according to the Article 9 of the Directive No. 98/79/EC | Annex IV excl. points 4+6 Full Quality Assurance |
|  | Annex IV, point 4 EC Design Examination (List A IVD only) |
| (please, check off the appropriate box/boxes ) | Annex V EC Type Examination |
|  | Annex VI EC Verification |
|  | Annex VII Production Quality Assurance |
|  | Another requirement (please, specify): |
| Required language versions of issued certificates: | Czech  English  other ( ) |

**APPLICANT’S DECLARATION:**

1. *We agree that product samples will not be returned after assessment.*
2. *We declare that we did not submit similar application for the same product to any other notified body.*
3. *We have signed the General Framework Agreement.*
4. *We and our staff do not have any relation to NB 1023 ITC that could jeopardize its independence or impartiality. The conformity assessment is only service provided by ITC to us.*

Date of Application Stamp and signature of applicant’s representative

**Detailed specification of the In Vitro Diagnostic Medical Device (IVD) subjected to the Application for conformity assessment*.***

|  |  |  |
| --- | --- | --- |
| Name and detailed description of the IVD: | | |
| List of IVD types and models covered by the Application (fill in particularly in the case that information on the table IVD MEDICAL DEVICE on the front page of this application is not sufficient): | | |
| GMDN code of the IVD (if the GMDN licence has been granted): | |  |
| List of documentation enclosed (*figures, drawings, instruction for use & installation, technical specification etc.*) as specified in the Annexes of the 98/79/EC directive as amended: | | |
| Is the IVD intended for self-testing? | Yes  No | |
| Intended use of the product (*detailed description*): | | |
| Has been this IVD product placed on the market already? | Yes  No | |
| If yes, write year of the first placing of the IVD on the market: |  | |
| If yes, which countries have been the IVD placed on the market in? |  | |
| Is the device designed and manufactured in a controlled quality system? | ☐ Yes ☐ No | |
| If yes, which standards does the quality system comply with? |  | |
| Is the quality system certified? | ☐ Yes ☐ No | |
| Are the test reports of the accredited testing laboratories available? | ☐ Yes ☐ No | |
| If yes, specify the test reports in list: |  | |
| List of documents concerning to manufacturer’s quality system (*certificates, audit reports, …*) | | |
| Another documents (*information, …*): | | |

Guidance for proper filling of particular fields in the application form

Data in the first table MANUFACTURER serve to identification of manufacturer and are on the certificate inscribed. There is strictly necessary to specify the exact name and address of the manufacturer (data shall be identical with those printed on the label of medical devices in question) and VAT number or other Identification number. Information about bank requisites (*bank name, account number, IBAN and/or SWIFT code*) is important for the sake of contract proposal and information about contact persons with e-mail, phone and fax shall speed up the data exchange.

The manufacturer who placed certain medical devices on the EU market and whom the Eudamed database registration code has been granted shall specify the granted code, called Eudamed Reference. Similarly, the manufacturer who registered certain medical devices at the Czech Ministry of Health and whom the Czech registration code (CA Reference) has been granted shall specify it.

The second table IVD MEDICAL DEVICE shall be duly completed with product trade names, which will be in case of positive certification decision written on relevant certificates, and the devices category as mentioned in the Article 9 and Annex II of the IVD Directive 98/79/EC. If the free space provided in the appropriate row of this table is not sufficient, the device details concerning type and/or model shall be filled into appropriate parts of the page 2.

Information in the further section shall be given in the case that the applicant’s company is an integral part of certain larger organization or trade association.

The third table CONFORMITY ASSESSMENT PROCEDURE shall specify one or more procedures of conformity assessment considering the classification and intended use mentioned above. The procedures applicable for the particular classes are specified in the Article 9 of the directive 98/79/EC (IVD). More than one procedure shall be chosen and checked off in certain cases, namely the combination of the Annexes V+VI or V+VII.

For IVD List A and Annex IV, two checkboxes should be checked off simultaneously, i.e. Annex IV excl. points 4+6 (Full quality assurance) plus Annex IV, point 4 (EC Design Examination).

Using the last line of this table, there is necessary to provide the Notified Body with information which language versions of the certificate(s) are requested.

The four declarations under the third table express the applicant’s agreement with the common conditions of the conformity assessment procedure applied by ITC, as well as declaration relating to the independence of manufacturer and ITC. The client’s signature (by handwriting) and date of application are strongly necessary.

On the second page, the device names shall be inscribed in the first row of the table provided together with description of the device, its main parts and critical materials. The second row is intended for information about all device types and models (including different trade names for the same device), if they have not been specified in the table IVD MEDICAL DEVICE on the front page of the application.

In case the manufacturer received licence from GMDN Agency, the assigned GMDN code.

Final part of the table on the page 2 shall provide an assessor with information whether these devices were placed on the market and under which conditions. The remaining rows are requesting for documentation describing both the product in question and the manufacturer’s quality system, including subcontracting etc.