**Annex 6. Information on the In Vitro Diagnostic Medical Device**

**Part A - Information on the in vitro diagnostic medical device collected for the purpose of certification**

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| Generic name of in vitro diagnostic medical device |  |
| Trade name of the medical device |  |
| Brief description of the product (intended use of the device) |  |
| Number of product versions covered by one technical documentation (same intended use/purpose of the product) |  |
| Nomenclature code GMDN or UMDNS or EDMA |  |
| Product code according to NBOG nomenclature |  |
| Qualification of the medical device | ☐ List A☐ List B☐ self-testing device |
| Conformity assessment carried out in accordance with Directive 98/79/EC as set out in the Annex: | ☐ Annex III, point 6 (device for self-testing)☐ Annex IV, with the exception of points 4 and 6 (List B product)☐ Annex IV, with the exception of point 6 (List A product) |
| Place of manufacture of the device (name of the entity and address, indicating the country).If any of the process steps (design, manufacture, final testing, sterilisation, packaging, storage, distribution) takes place at another location, indicate this location (name of the entity and address, indicating the country). |  |
| Language of technical documentation and quality system | ☐ Polish☐ English |
| Instructions for use / draft instructions and/or promotional materials | *Annex to the application* |
| Accessories specifically designed for use with and sold in conjunction with the product |  |
| Other useful information about the device |  |
| Required Declarations |
| Has an application been lodged to another notified body for the assessment of a quality system relating to the same in vitro diagnostic medical device for which this application is submitted?  | ☐ Yes | ☐ No |
| The manufacturer of the in vitro diagnostic medical device to which this application relates shall undertake to fulfil the obligations imposed by the quality system approved. | ☐ Yes | ☐ No |
| The manufacturer of the in vitro diagnostic medical device to which this application relates shall undertake to keep the approved quality system adequate and efficacious. | ☐ Yes | ☐ No |
| The manufacturer of a medical device for in vitro diagnostics, which is the subject of this application, undertakes to institute and keep up to date a systematic procedure to review experience gained from devices in the post-production phase and to implement appropriate means to apply any necessary corrective action and notification as referred to in Annex III (section 5) to Directive andto act in accordance with the provisions of Chapter 9 of the Polish Act of 20 May 2010 on medical devices (Polish Journal of Laws 2010 No. 107, item 679, as amended) in the event of obtaining information about the occurrence of a medical incident. | ☐ Yes | ☐ No |
| Name, date and signature of person authorised by the manufacturer | *I hereby confirm the above statements from the section "Required Declarations" and apply for certification of the medical device to which this application relates.*………………………………………………………………………………… |
| To be completed by CeCert |
| Does the above mentioned product, according to the attached instructions for use/draft instructions and/or promotional material, meet the definition of an in vitro diagnostic medical device? | ☐ Yes | ☐ No |
| ……………………………………………………………………………………Date and signature of the Director of the Medical Devices Certification Department |
| Is the manufacturer's qualification of the in vitro diagnostic medical device correct? | ☐ Yes | ☐ No\* |
| *\* fill in if „No”*Correct qualification according to CeCert:☐ list A☐ list B☐ self-testing device |
| ……………………………………………………………………………………Date and signature of the Director of the Medical Devices Certification Department |
| Product code according to the NBOG nomenclature |  |
| ……………………………………………………………………………………Date and signature of the Director of the Medical Devices Certification Department |
| Has the GMDN or UMDNS or EDMA code been correctly selected for the product? | ☐ Yes | ☐ No\* |
| *\* fill in if „No”*Correct code sent by the manufacturer after discussion with CeCert: ………………………………………………………………………………………………………………………………………………………Date and signature of the Director of the Medical Devices Certification Department |
| Based on the above information, this application of the manufacturer is accepted and it is decided to initiate the CeCert certification process for the in vitro diagnostic medical device | ☐ Yes | ☐ No\* |
| *\* fill in if „No”*Reasons for rejecting the manufacturer's application: |
| ……………………………………………………………………………………Date and signature of the Director of the Medical Devices Certification Department |

**Part B – Information on the in vitro diagnostic medical device collected in relation to a change**

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| Certificate No. to which the change relates |  |
| Name of the device affected by the change |  |
| Detailed description of the change |  |
| Revised/ammended device documentation | *Annex to the application* |
| Other useful information about the change |  |
| Name, date and signature of person authorised by the manufacturer | ………………………………………………………………………………… |
| To be completed by CeCert |
| Does the change, according to the information provided by the manufacturer, require an expert evaluation of the product documentation? | ☐ Yes | ☐ No\* |
| *\*ill in if „No”*Justification: |
| ……………………………………………………………………………………Date and signature of the Employee carrying out the change assessment |
| Does the change, according to the information provided by the manufacturer, requires an additional audit? | ☐ Yes | ☐ No\* |
| *\* ill in if „No”*Justification: |
|  | ……………………………………………………………………………………Date and signature of the Employee carrying out the change assessment |