**Application number** \*) **for medical device conformity assessment acc. to Art. 52 Regulation (EU) 2017/745**

*\*) The number is filled in by the ITC*

| **1.** | **Basic identification data of the manufacturer** | |
| --- | --- | --- |
| 1.1. | Manufacturer's company name: |  |
| 1.2. | Legal address of the manufacturer's registered office: |  |
| 1.3. | Company identification number (from the Commercial Register, etc.): |  |
| 1.3.1. | Single registration number SRN  (see MDR Art. 31, par. 2) |  |
| 1.4. | Name of statutory representative: |  |
| 1.4.1. | Contact details of the manufacturer's statutory representative: | phone: |
| e-mail: @ |
| 1.5. | Name of the contact person, if different from the statutory representative: |  |
| 1.5.1. | Contact person data: | phone: |
| e-mail: @ |
| 1.6. | The manufacturer is a member of a group of manufacturers (group): | NO  YES |
| 1.6.1. | If the manufacturer is a member of the group, provide a link to a file or website containing a list of members: |  |

| **2.** | **Type of application** (tick one corresponding item) |
| --- | --- |
|  | New application for medical device certification |
|  | Request for approval of a change in a medical device |
|  | Request for approval of a change in the quality management system |
|  | Request for change of the covered range of medical devices |
|  | Request for transfer from another notified body to NB 1023 ITC |
|  | Application for certificate renewal (application for recertification) |
| **3.** | **History of application** (tick one corresponding item, or fill in the NB number) |
|  | Application relating to the same device and quality system has not been lodged in the past with another notified body |
|  | Application has already been submitted to the notified body No. NB \_\_\_ and has been refused |
|  | Application has already been submitted to the notified body No. NB \_\_\_ and has been taken back |

| **4.** | **Basic identification data of a medical device** | |
| --- | --- | --- |
| 4.1. | Type of medical device: |  |
| 4.2. | Trade name(s) of the medical device: |  |
| 4.3. | Risk class of the device: (tick only one of the options, as a separate application is required for each class) | Im Class I devices with measuring function |
| Ir Class I reusable surgical instruments |
| Is Class I devices placed on the market in sterile condition |
| IIa Class IIa devices |
| IIb Class IIb non-implantable devices |
| IIb Class IIb implantable devices |
| III Class III devices |
| 4.4. | Basic UDI-DI:  (only for Class III devices and implantable Class IIb devices other than WET) |  |
| 4.5. | Conformity assessment procedure chosen: | Annex IX(I+III) Quality management system  Annex IX(II) Assessment of the technical documentation  Annex XI(A) Production quality assurance, sec. 10  Annex XI(A) for MD with an EU type-examination certificate |
| 4.6. | Does MD contain human or animal tissues or their derivatives? | NO  YES |

| **5. Manufacturer's declaration** |
| --- |
| **The manufacturer declares that:** |
| - this application for conformity assessment of a medical device according to Regulation (EU) 2017/745, as amended (MDR) is filled in correctly and does not contain false or misleading information;  - did not apply simultaneously to another notified body;  - if he has previously lodged an application relating to the same device and quality system with another notified body, and has withdrawn it or been refused, information on such application shall be included in the accompanying documentation;  - signed the General Framework Agreement (GFA-MDR) concluded with the Institute for Testing and Certification, Inc. which is a Notified Body NB 1023;  - neither the company nor the manufacturer's employees have any relationship with the ITC that could compromise the independence and impartiality of the ITC's decisions, and the only type of service that the ITC has provided or is providing to the applicant is conformity assessment and / or product testing;  - the application shall be accompanied by the documentation in the scope, structure and form specified by the WIDAR application;  - the documents and information accompanying the application are correct, objective and do not infringe the rights of third parties, including copyright;  - is aware that the provision of false information, breach of the provisions of the GFA-MDR Framework Agreement, the obligations set out in section 6 of this application or the relevant provisions of the MDR and the MDCG Implementing Guidelines will result in the NB 1023 Notified Body refusing to issue a certificate, or suspending or revoking an already issued certificate, and notifying the competent authorities. |

| **6. Manufacturer 's commitment** |
| --- |
| **The manufacturer undertakes:** |
| - maintain the quality management system in a usable and effective condition throughout the life cycle of the devices concerned and fulfill all the obligations arising out of the approved quality system;  - apply the procedures put in place to ensure that the quality management system remains adequate and effective;  - apply the procedures put in place to update the post-market surveillance system and, where applicable, the PMCF plan, and the procedures to ensure compliance with the obligations arising from the vigilance provisions set out in Articles 87 to 92 of the MDR;  - comply with the provisions of the GFA-MDR General Framework Agreement;  - plan, establish, implement and update a post-market surveillance system within the meaning of Article 83 of the MDR;  - report to the competent authorities and the ITC any serious incident and any field safety corrective action related to devices placed on the EU market under Article 87 of the MDR;  - report to the competent authorities and the ITC any statistically significant increase in the frequency or severity of incidents that are not serious incidents or that are expected undesirable side effects that could have a significant impact on the benefit-risk analysis (trend reporting) under Article 88 MDR;  - with the exception of Class I medical devices, prepare and update at regular intervals a periodic safety update report PSUR and submit it in the manner described in Article 86 to the Notified Body NB 1023;  - enable the notified body NB 1023 to carry out all necessary audits, including on-site audits and unannounced audits, and ensure the possibility of carrying out audits at the premises of its subcontractors;  - inform the notified body NB 1023 of any intention to change the quality management system, the scope of devices covered or the approved design of devices and wait for the implementation of the change for a positive decision of the notified body NB 1023;  - notify the NB 1023 of the intention of any change related to the medicinal substance incorporated in the device and await the positive opinion of the medicinal products authority consulted, the issuance of which will be mediated by the notified body NB 1023;  - for at least 10 years and, in the case of implantable devices, for at least 15 years from the date the last device was placed on the market, keep at the disposal of the competent authorities the EU declaration of conformity, the quality management system documentation, the documentation relating to the design or type-examination of the device, information on changes and all decisions and reports of the notified body NB 1023; the third country manufacturer undertakes to entrust this obligation to an authorized representative in the EU;  - to announce ITC membership in a group of manufacturers (a group within the meaning of Section 79 of Act No. 90/2012 Coll. on Business Corporations), if it occurs;  - to comply with the provisions of the guidelines issued by the MDCG Coordination Group established under Article 103 of the MDR. |

The undersigned representative of the manufacturer declares that he is authorized to act on behalf of the manufacturer in respect of this application and is aware of the consequences of providing incorrect information.

**Name of manufacturer's representative:**

**Date and signature:** 202X-XX-XX ................................................

*signature*

**Application review No. by notified body**

**NB 1023 acc. to Annex VII, section 4.3. MDR**

| **Review of aspects of the application** (to be completed by the ITC) | | | |
| --- | --- | --- | --- |
| MD codes according to Regulation (EU) 2017/2185: | |  | |
| a) | The product is qualified as a medical device and its classification as proposed by the manufacturer in section 4, point 4.3 of the application respects the classification rules in the Annex VIII of the MDR. | | YES  NO |
| b) | The conformity assessment procedure chosen by the manufacturer as described in section 4, point 4.5 of the application is applicable to the medical device concerned in accordance with the provisions of Article 52 of the MDR. | | YES  NO |
| c) | The application is complete with regard to the requirements of the conformity assessment procedure requested by the manufacturer (see section 4, point 4.5 of the application). | | YES  NO |
| d) | Device codes according to Regulation (EU) 2017/2185 and the conformity assessment procedure chosen by the manufacturer as specified in section 4, point 4.5 of the application are covered by the scope of NB 1023 notification. | | YES  NO |
| e) | The Notified Body NB 1023 currently has sufficient staff to carry out all the activities of the required conformity assessment procedure for the device. | | YES  NO |
| f) | The information provided in the application or its annex shall not contain any information that could potentially lead to a conflict of interest or a suspicion of a potential conflict of interest.. | | YES  NO |
| g) | The manufacturer made the annex to the application available to the Notified Body NB 1023 in the WIDAR application within the specified time after receipt of the application. | | YES  NO |
| h) | The manufacturer has signed the currently valid version of the GFA-MDR General Framework Agreement and follows its provisions. | | YES  NO |
| i) | The manufacturer has remedied the formal deficiencies in the application that were brought to its attention when the application was registered. | | N/A  YES  NO |
| j) | The manufacturer informed the notified body that he had lodged a previous application with another NB and withdrew it or that it had been rejected. | | N/A  YES  NO |

**Opinion on the application:**

The request was accepted by the notified body NB 1023.

The application was rejected by the notified body NB 1023 due to insufficient staff capacity.

The application was rejected by the notified body NB 1023 for the following reason:

**The application has**

**been reviewed by:**

**Date and signature:** ................................................

*signature*