|  |
| --- |
| **Contract number** |
| **Do not fill in, to be filled by EZÚ.** |

|  |
| --- |
| **APPLICATION**  for Conformity Assessment |

*Two separate applications need to be filled in for conformity assessment in accordance with both government regulations.*

*For conformity assessment according to two and more annexes, a separate application needs to be filled in for each annex.*

*A separate application needs to be filed for each class III medical device.*

|  |  |
| --- | --- |
| **of medical devices**  **in accordance with Government Regulation No. 54/2015 Coll.** | **of active implantable medical devices pursuant to Government Regulation No. 55/2015 Coll.** |
| *(hereinafter referred to as GR54)* | *(hereinafter referred to as GR55)* |
| **-** Complete Quality Assurance System **– Annex No. 2** | **-** Complete Quality Assurance System **– Annex No. 2** |
| **-** EC Type Examination **– Annex No. 3** | **-** EC Type Examination **– Annex No. 3** |
| **-** EC Verification **– Annex No. 4** | **-** EC Verification **– Annex No. 4** |
| **-** Production Quality Assurance **– Annex No. 5** | **-** Production Quality Assurance **– Annex No. 5** |
| **-** Medical Device Quality Assurance **– Annex No. 6** |  |
| **New Certification** |  |
| **Recertification of Certificate No.:** MED……………. | |
| **Extension of Certificate No.:** MED……………. | |

|  |
| --- |
|  |

**1 CLIENT**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| The Client is: | | OEM manufacturer | | | VAT payer | |
| OBL manufacturer**\*** | | | Natural person | |
| Authorized representative | | | Legal person | |
| Business name: | | | | | | |
| Address: | | | | | | |
| Incorporated in the Companies Register kept by: | | | | | | |
| Company identification No.: | Tax identification No.: | | | Bank account No.: | | |
| Contact person (name): | | | Tel.: | | | E-mail: |
| Person authorized for contract performance: | | | Position: | | | |
| Statutory representative: | | | Position: | | | |

\* See page 2

|  |  |
| --- | --- |
| \* If the Client is an OBL manufacturer, information about the OEM manufacturer needs to be included:  *If there are more OEM manufacturers, a separate application needs to be filed for each of them.* | |
| OEM manufacturer business name: | OEM certificate No.: |
| OEM manufacturer address: | Expiry date of OEM manufacturer certificate: |
| Notified body that issued the OEM manufacturer certificate: | Expiry date of OEM – OBL contract: |

**2 OTHER CERTIFICATION SITES (development, production, branch, plant and other)**

*Add lines if necessary.*

Branches, production sites, plants, agencies and other

|  |  |  |
| --- | --- | --- |
| Business name | Address | Processes and activities |
|  |  |  |
|  |  |  |
|  |  |  |

Critical subcontractors and crucial suppliers of products, components and services

|  |  |  |
| --- | --- | --- |
| Business name | Address | Product / Service |
|  |  |  |
|  |  |  |
|  |  |  |

External organizations affecting product conformity (external processes)

*List suppliers of outsourced processes (e.g. design and development etc.)*

|  |  |  |
| --- | --- | --- |
| Business name | Address | Processes |
|  |  |  |
|  |  |  |
|  |  |  |

**3 NON-EU PRODUCER REPRESENTED BY AN AUTHORIZED AGENT**

|  |
| --- |
| Manufacturer business name: |
| Address: |
| Contact person (name, e-mail, phone): |

**4 MEDICAL DEVICES SUBJECT TO CERTIFICATION**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Class: | | | | | |
| I sterile | I with measuring function | I sterile with measuring function | IIa | IIb | III |
| System or set - sterilized (pursuant to Section 5(4) of GR 54) | | | | | |

|  |
| --- |
| Medical Device (MD) categories by MD codes:  *If the medical device can be assigned to more MD codes, all codes need to be listed.* |
| MD 0100 General non-active, non-implantable medical devices |
| MD 0101 Non-active devices for anaesthesia, emergency and intensive care |
| MD 0102 Non-active devices for injection, infusion, transfusion and dialysis |
| MD 0103 Non-active orthopaedic and rehabilitation devices |
| MD 0104 Non-active medical devices with measuring function |
| MD 0105 Non-active ophthalmologic devices |
| MD 0106 Non-active instruments |
| MD 0107 Contraceptive medical devices |
| MD 0108 Non-active medical devices for disinfecting, cleaning, rinsing |
| MD 0109 Non-active devices for in vitro fertilisation (IVF) and a ssisted r eproductive t echnologies (ART) |
| MD 0110 Non-active medical devices for ingestion |
| MD 0200 Non-active implants |
| MD 0201 Non-active cardiovascular implants |
| MD 0202 Non-active orthopaedic implants |
| MD 0203 Non-active functional implants |
| MD 0204 Non-active soft tissue implants |
| MD 0300 Devices for wound care |
| MD 0301 Non-active MD: Bandages and wound dressings |
| MD 0302 Non-active MD: Suture material and clamps |
| MD 0303 Other medical devices for wound care |
| MD 0400 Non-active dental devices and accessories |
| MD 0401 Non-active dental equipment and instruments |
| MD 0402 Non-active MD: Dental materials |
| MD 0403 Non-active MD: Dental implants |
| MD 1100 General active medical devices |
| MD 1101 Devices for extra-corporal circulation, infusion and haemopheresis |
| MD 1102 Respiratory devices, devices in cluding hyperbaric chambers for oxygen therapy, inhalation anaesthesia |
| MD 1103 Devices for stimulation or inhibition |
| MD 1104 Active surgical devices |
| MD 1105 Active ophthalmologic devices |
| MD 1106 Active dental devices |
| MD 1107 Active devices for disinfection and sterilisation |
| MD 1108 Active rehabilitation devices and active prostheses |
| MD 1109 Active devices for patient positioning and transport |
| MD 1110 Active devices for in vitro fertilisation (IVF) and assisted reproductive technologies (ART) |
| MD 1111 Active MD: Software |
| MD 1112 Active MD: Medical gas supply systems and parts thereof |
| MD 1200 Active MD: Devices for imaging |
| MD 1201 Active MD: Imaging devices utilising ionizing radiation |
| MD 1202 Active MD: Imaging devices utilising non-ionizing radiation |
| MD 1300 Monitoring devices |
| MD 1301 Monitoring devices of non-vital physiological parameters |
| MD 1302 Monitoring devices of vi tal physiological parameters |
| MD 1400 Devices for radiation therapy and thermo therapy |
| MD 1401 Devices utilising ionizing radiation |
| MD 1402 Devices utilising non-ionizing radiation |
| MD 1403 Devices for hyperthermia / hypothermia |
| MD 1404 Devices for (extracorporal) shock-wave therapy (lithotripsy) |
|  |
| AIMD 0100 General active implantable medical devices |
| AIMD 0101 Active implantable medical devices for stimulation / inhibition |
| AIMD 0102 Active implantable medical devices delivering drugs or other substances |
| AIMD 0103 Active implantable medical devices substituting or replacing organ functions |
|  |
| MDS 7001 Medical devices incorporating medici nal substances, according to Directive 2001/83/EC |
| MDS 7002 Medical devices utilising tissues of animal origin, including Directive 2003/32/EC |
| MDS 7003 Medical devices incorporating derivat es of human blood, according to Directive 2000/70/EC, amended by Directive 2001/104/EC |
| MDS 7004 Medical devices referencing the Directive 2006/42/EC on machinery |
| MDS 7006 Medical devices in sterile condition |
| MDS 7007 Medical devices utilising micromechanics |
| MDS 7008 Medical devices utilising nanomaterials |
| MDS 7009 Medical devices utilising biological active coatings and/or materials or being wholly or mainly absorbed |
| MDS 7010 Medical devices incorporating software /utilising software /controlled by software |
|  |
| Other: |

|  |
| --- |
| Medical device (generic group name pursuant to Section 14 of Decree No. 62/2015 Coll.): |
| GMDN code (generic group name pursuant to Section 14 of Decree No. 62/2015 Coll.): |
| Trade name: |
| Model (type)/version: |
| *If the generic group contains more than one medical device (trade name, model), a complete list of the medical devices included in this group needs to be attached to the application, including the respective types, models, versions etc. and descriptions of how the individual models differ.* |
|  |
| Applied classification rule and particular rule item pursuant to Annex No. 9 of GR54: |
| Intended purpose: |
| Brief description: |
| *Brief description means basic technical information and description of the basic function of active medical devices, for other medical devices, a brief description means basic technical information, description of the basic function and information on product composition and materials used.* |
| Active substance: |
| Intended purpose of active substance: |

List of applied European harmonized standards:

*Add lines if necessary.*

|  |  |  |
| --- | --- | --- |
| Full standard identification (including year of issue) | Applied generally | Applied partially |
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MD sterility:

|  |  |
| --- | --- |
| Product supplied as sterile: | YES /  NO |
| Product to be sterilized: | YES /  NO |

Sterilization type:

|  |  |
| --- | --- |
| Sterilization by radiation | Sterilization by ethylene oxide |
| Sterilization by wet heat | other; specify: |

List of technical components with respective model identification (for MDs of all classes except for class III):

*Add lines if necessary.*

|  |  |
| --- | --- |
| *TF identification* | *Identification of respective models* |
|  |  |
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Design Dossier identification (only class III)

|  |  |
| --- | --- |
| *DD identification* | *Model identification* |
|  |  |

**5 OTHER MEDICAL DEVICE SPECIFICATION**

|  |  |
| --- | --- |
| Medical device containing medication as its integral component | YES /  NO |
| Identification of used medication: | |
| Purpose of used medication: | |
| EDQM certificate No. (if any): | |
| Medical device containing tissues of animal origin | YES /  NO |
| Medical device containing derivatives of human blood | YES /  NO |
| Medical device containing phthalates | YES /  NO |
| Medical device subject to requirements of GR 176/2008 Coll., on Technical Requirements for Machinery | YES /  NO |
| Medical device utilising micromechanics | YES /  NO |
| Medical device utilising nanotechnology | YES /  NO |
| Medical device utilising biological active coatings and/or materials or being wholly or mainly absorbed | YES /  NO |
| Medical device utilising source of ionizing radiation | YES /  NO |

**6 OTHER CERTIFICATIONS**

|  |  |
| --- | --- |
| The manufacturer has EN ISO 13485 certified system | YES /  NO |
| Manufacturer transferred from another notified body | YES /  NO |
| Reason for change of notified body: | |
| Name of previous notified body: | |
| Previous certificate No.: | |
| Previous certificate validity: | |

**7 QUESTIONNAIRES**

VERIFICATION QUESTIONNAIRE (fill in if applying procedure described in Annex No. 4)

|  |  |
| --- | --- |
| Application for verification | by individual review and testing  by statistics |
| Production batch scale (number of items in a batch) |  |
| Batch serial number scale\*  *\*If the serial numbers are not consecutive, a complete list of serial numbers needs to be submitted as an application attachment.* |  |

QUALITY ASSURANCE QUESTIONNAIRE (fill in if applying procedure described in Annex No. 2, 5 and 6)

|  |  |
| --- | --- |
| Number of employees involved in manufacturing (including branches) subject to certification: |  |
| Number of branches involved in manufacturing subject to certification: |  |

**Manufacturer performs:**

|  |  |  |
| --- | --- | --- |
| * Design and development | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Manufacture | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Final assembly | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Output check | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Product testing | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Packaging | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Sterilization | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Clean space | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

|  |  |  |
| --- | --- | --- |
| * Storage | | YES |
| NO |
| EXTERNAL | Name and address of external supplier: | |
| Note: |  | |

**Product activity**

|  |  |  |
| --- | --- | --- |
| * Critical components | | YES |
| NO |
| Identification of purchased components: |  | |

|  |  |  |
| --- | --- | --- |
| * Intermediate products | | YES |
| NO |
| Identification of purchased intermediate products: |  | |

|  |  |  |
| --- | --- | --- |
| * Critical services | | YES |
| NO |
| Identification of purchased services: |  | |

**8 MANUFACTURER'S DECLARATION**

**The Manufacturer represents:**

1. The same application has not been submitted to another notified body;
2. The Manufacturer shall meet the obligations arising from the approved quality system pursuant to Annex\* No. 2, No. 5, No. 6;
3. The Manufacturer shall keep the quality system adequate and effective pursuant to Annex\* No. 2, No. 5, No. 6;
4. The Manufacturer shall submit correct and complete documentation required for conformity assessment to the notified body;
5. The Manufacturer shall inform the competent authorities and the notified body of EZÚ, s. p. in the event of any undesirable incident;
6. The Manufacturer shall inform the notified body of EZÚ, s. p. about any change of conformity assessment conditions;
7. The Manufacturer shall implement and update a systematic procedure of evaluating the experience acquired in relation to the manufactured medical devices and implement adequate corrective measures as necessary.

*\* Do not fill in if not applying the procedure described in the above-mentioned annexes.*

**9 CONDITIONS FOR FILING THE APPLICATION**

1. An application that is correct and signed is considered binding. Based on the application, the scope of conformity assessment is defined. Any amendments to a filed application can be made solely by filing a new application. If a new amended application is filed, the conformity assessment process starts anew.
2. The application is to be filled in electronically, printed and signed.
3. Two separate applications need to be filled in for conformity assessment in accordance with both government regulations.
4. For conformity assessment according to two and more annexes, a separate application needs to be filled in for each annex.
5. One application is to be filled in for each MD subgroup or generic group.
6. A separate application needs to be filed for each class III medical device.
7. A separate application is required for each OEM for OBL certification.
8. Technical documentation in line with the requirements of the applicable governmental regulation and in accordance with the selected conformity assessment procedure (see "CE Certification Requirements" at http://ezu.cz/ke-stazeni/objednavka) needs to be submitted together with the binding application.
9. Only complete and correctly filled applications including technical documentation will be accepted. If the application is incomplete, the client will be called to complete it. If the application is not completed after a call for completion, such an application may be rejected.
10. If the application cannot be accepted, EZÚ, s.p. will inform the client in writing.

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|  |  |  |
| --- | --- | --- |
| **Date and place** |  | **Client’s signature** |
|  |  |  |
|  |  |  |
|  |  | Official stamp: |

|  |
| --- |
|  |
| **Do not fill in, to be filled by EZÚ.** |

Application assessment by Product Manager:

|  |  |
| --- | --- |
| Application complete: | YES /  NO |
| Application formally correct: | YES /  NO |
| Medical device: | YES /  NO |
| Medical device within the scope of EZÚ, s.p. notification: | YES /  NO |
| Notified body has qualified employees for the conformity assessment process of the MD: | YES /  NO |
| Correct risk classification of the medical device: | YES /  NO |
| Medical device containing medication as its integral component: | YES /  NO |
| Submitted documentation complete: | YES /  NO |
| Application statement: | |

Electrotechnical Testing Institute as notified body No. 1014: Based on the above findings the application is

|  |  |
| --- | --- |
| **ACCEPTED** | **REJECTED** |

|  |  |  |
| --- | --- | --- |
| **Date** |  | **Name and signature of notified body representative** |
|  |  |  |
|  |  |  |