1. **IMPORTANT INFORMATION AND APPLICATION TYPE**

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| --- |
| This application form consists of Annexes. This form must be filled in every application. Depending on application type, annexes of this form must be filled. Filling this form complete and correctly is crucial for preparation of agreement and determination of services correctly.  Please tick the boxes below for the annexes you have filled in;  FR.MED.01 Annex 01 Application Form - Sites Covered by The Same QMS  FR.MED.01 Annex 02 Application Form - Critical Supplier and/or Subcontractor Info  FR.MED.01 Annex 03 Application Form - Product Information Table  FR.MED.01 Annex 06 Application Form - Info Related to Change of NB |

|  |  |
| --- | --- |
| **Application Type** | **Regulation (EU) 2017/745** |
| **Initial Application** | (Annex-1, Annex-2, Annex-3 shall be filled.) |
| **Transfer** | (Annex-1, Annex-2, Annex-3, Annex-6 shall be filled.) |
| **Re-certification** | (Annex-1, Annex-2, Annex-3 shall be filled.) |
| **Change Assessment** | FR.MED.51 and Applicable Annexes of Application Form |
| **Application for QMS Certification According to Article 16 Section 3** | (Annex-1, Annex-2, Annex-3 shall be filled.) |
| - The previously certified customers shall notify MCA for any plan for changes about the approved quality management system or systems or to the product-range covered, the approved design of a device, the intended use of or claims made for the device, the approved type of a device, and any substance incorporated in or utilized for the manufacturing of a device and being subject to the specific procedures in accordance with the specific procedures of the Regulation (EU) 2017/745, if any, by means of the FR.MED.51 Change Notification Form and this application form.  - SZUKOREA is subcontracted company by MCA as International Contact Office. | |

1. **SERVICE PROVIDING COMPANY INFORMATION**

|  |  |
| --- | --- |
| **Company Title** |  |
| **Company Address**  **(Address of its registered place of business)** |  |
| **Company EUDAMED SRN Number** |  |
| **Authorised Signatory Name** |  |
| **Telephone** |  |
| **Fax** |  |
| **Email** |  |
| **Web address** |  |
| **Tax Office / Number** |  |
| **Management Representative** |  |
| **Contact Person Name/Job Title** |  |
| **Contact Information (e-mail, telephone)** |  |
| **If your company is a part of a bigger entity; please state the name of this entity** |  |

1. **MANUFACTURER\* INFORMATION**

Please select following information related to the application.

|  |  |
| --- | --- |
| **Does the company outsource design/manufacturing processes of the applied product completely to another manufacturer?** | Yes  No |
| **Does the company re-label the applied product which is already in the market and manufactured/designed by another company?** | Yes  No |
| *When “****yes****” is selected the outsourcing company shall be identified in application form in* ***Annex 2.*** | |

\*Manufacturer: A natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark.

1. **EUROPEAN UNION AUTHORISED REPRESENTATIVE**If the company, which will obtain conformity assessment service, is located out of European Economic Area (EEA), this section must be filled.

|  |  |
| --- | --- |
| **Name** |  |
| **Address** |  |
| **EUDAMED SRN Number** |  |
| **Authorised Signatory Name** |  |
| **Telephone** |  |
| **Fax** |  |
| **E-mail** |  |
| **Web address** |  |
| **Tax Office / Number** |  |
| **Management Representative Name** |  |
| **Contact Person Name/Job Title** |  |

1. **REQUIRED SCOPE**

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|  |
| Please state the product and product groups which are demanded for certification. Required scope can be changed by MCA according to assessment result.  Please give detailed information related product and product groups in Annex 3. |

1. **TOTAL NUMBER OF TECHNICAL DOCUMENTATION**

|  |  |
| --- | --- |
| **Total number of Technical Documentation for the applied products** |  |

1. **CONFORMITY ASSESSMENT ROUTES FOR REGULATION (EU) 2017/745**

Please select following conformity assessment route(s) related to the application.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Class III non-implantable devices** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation for every device** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class III implantable devices** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation for every device** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class III custom-made implantable devices** |  | **Annex IX Chapter I** |  | **Annex XI Part A** |
| **Class IIb implantable devices –non-WET1** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation for every device** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class IIb implantable devices – WET1** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation assessed per generic device group** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class IIb non-implantable devices, non-rule 12,**  **non-WET1** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation assessed per generic device group** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class IIb devices**  **Annex VIII Rule 12** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation assessed per generic device group** |  | **Annex XI Part-A Production Quality Assurance** (If there is a current EU Type Examination Certificate2) |
| **Class IIa devices** |  | **Annex IX QMS Chapter I, III**  **Annex IX Chapter II Technical Documentation assessed per device category** |  | **Annex XI Part-A Production Quality Assurance**  **Annex II and III Technical Documentation assessed per device category** |
| **Class Is, Im, Ir devices** |  | **Annex IX QMS Chapter I, III\***  **\*(Limited to sterility, metrology or re-use aspects surgical instruments)** |  | **Annex XI Part-A Production Quality Assurance\***  **\*(Limited to sterility, metrology or re-use aspects surgical instruments)** |

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| (1) WET Devices: Sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips or connectors for which the clinical evaluation is based on sufficient clinical data and is in compliance with the relevant product-specific CS, where such CS is available.  (2) EU Type Examination certificate is required for these products from another Notified Body. Please send the certificate together with the application form when this route is chosen. The manufacturer is contractually obliged to inform the MCA about changes to the EU-type examination test/certificates. |

1. **OTHER INFORMATION**

|  |  |
| --- | --- |
| **If the refusal of the certification application to another certification/notified body for the product(s) in this application, please state the name, the decision and the justification of the body.** |  |
| **If the company have got valid or invalid certificate(s) of the product(s) in this application, please state the name(s) of the Certification/Notified Body(s) and the type(s) of the certificate(s). If the certificate(s) is invalid, please state the reason(s) of the invalidation. Please send to us these documents additional to this application.** |  |
| **If the company has been signed an agreement with another notified body for the product(s) in this application, please state the name of the body and the reason(s) of recession of the agreement.** |  |

1. **RECERTIFICATION**Please fill in this section, only if the company has a valid certificate issued by MCA and extension of certificate validation period for these certificates is requested.

|  |  |
| --- | --- |
| **Current Certificate Number** |  |
| **Does the certificate to be recertified referenced to an EU certificate type examination certificate?** | Yes  No (If yes, please send this certificate additionally.) |
| **Are there any unapproved changes in the products design?** | Yes  No |
| **Is the classification of the products same?** | Yes  No |
| The company shall provide the updated technical documentation together with a summary report for below changes;  - All changes to the originally approved device, including changes not yet notified.  - Experience gained from post-market surveillance.  - Experience from risk management.  - Experience from updating the proof of compliance with the GSPR.  - Experience from reviews of the clinical evaluation, including the results of any clinical investigations and PMCF.  - Changes to the requirements, to components of the device or to the scientific or regulatory environment.  - Changes to applied or new harmonised standards, CS or equivalent documents.  - Changes in medical, scientific and technical knowledge, such as: — new treatments, — changes in test methods, — new scientific findings on materials and components, including findings on their biocompatibility, — experience from studies on comparable devices, — data from registers and registries, — experience from clinical investigations with comparable devices.  - Summary of PMS findings.  - Summary of PMCF findings. | |

1. **LANGUAGE INFORMATION**

a) Technical Documentation and any related correspondence shall be in English Language. As a general principle, if any of the information requested in some part of technical documentation is not available in English, the manufacturer should provide translations of documents (procedures, instructions, protocols, reports, etc.) in Technical Documentation.

b) MCA will create records in English Language.

c) In case of different languages are spoken or some part of QMS documentation is not available in English, a translator shall be used in the audits. In this situation, before assignment, FR.275 Confidentiality and Impartiality Commitment for Translators shall be signed by the translator.  
d) The correspondence language for conformity assessment activities shall be in English Language.

|  |  |  |
| --- | --- | --- |
| **Requested Audit Language** | English | Other, please state: |
| **Language of QMS Documentation** | English | Mixed, please state: |
| **Language of QMS Records** | English | Mixed, please state: |
| **Language of Legal Documents** | English | Mixed, please state: |
| **Please state regulations, standards, common specifications and other legislations which should be related to products and QMS System.** |  | |
| **If consultation service has been taken, please state the consultant company or the person.** |  | |
| **How do you have information about MCA?** |  | |

1. **REQUIRED DOCUMENTS FOR APPLICATION**

|  |  |
| --- | --- |
| **Document Descriptions** | |
| **Quality Manual** | √ |
| **Instruction for Use** | √ |
| **Legal documents indicates the records of location** | √ |
| **Authorised signature who signs the agreement** | √ |
| **Official document indicates number of workers** | √ |
| **Technical Documentation**  **The technical documentation should mainly include the following subjects;**  **•** The intended use including confirmation that the product is a medical device and it's correct classification,  **•** The validity of the General Performance and Safety Requirements checklist, especially when harmonized standards have not been applied in full,  • Benefit-Risk Analysis and Risk Management,  • Product Verification and Validation (which hone is related with device; Biocompatibility, Electrical safety and electromagnetic compatibility (EMC), Software Verification and Validation, Stability, including shelf life),  • Performance and Safety – Design Verification and Validations,  • Information supplied by the manufacturer (label, instructions for use, etc.)  • Clinical Evaluation,  • Post Market Surveillance & Post Market Clinical Follow-up,  • The validity of the requirements for devices incorporating medicinal substances - (if related),  • The validity of the requirements for devices composed of substances that are absorbed by or locally dispersed in the human body (Rule 21 devices) (if related),  • The validity of the requirements for devices containing CMR or endocrine-disrupting substances referred to in GSPR 10.4.1 of Annex I of MDR (if related),  • The validity of the requirements for packaging and transport,  • The validity of the requirements for sterilisation (if related),  • The validity of the requirements reusable surgical instruments (if related),  • The validity of the requirements for devices with a measuring or diagnostic function (if related),  • The validity of the requirements for devices intended to be connected to other devices to operate as intended (if related),  • The validity of the requirements magnetic resonance imaging safety of implants (if related),  • Declaration of conformity or the draft thereof | √ |
| **Special attention shall be paid to the following in these documents:** | √ |
| **Procedures for monitoring and verification of the design of medical devices, in their documentation** | √ |
| **Quality Management System Documentation (Procedures, Instructions, Lists, Plans, Forms etc.)** | √ |
| **Quality Certificates of Critical Suppliers** | √ |
| **Copies of Already Existing Certificates (such as QMS, GMP, national legislation certificates, Own-Laboratory Accreditation Certificates, etc)** | √ |
| **Documents related EU Authorised Representative (AR) (if relevant);**   * Agreement between the company and AR, * The quality system certificate of AR, * The documents that are shown that AR implements Annex IX Chapter III requirements of MDR. | √ |
| **Documents justifying classification and information about products** | √ |
| **A draft of an EU declaration of conformity in accordance with Article 19 and Annex IV for the device model covered by the conformity assessment procedure** | √ |
| **Medicinal product master file for devices incorporating medicinal product (if related)** | √ |
| **For devices incorporating medicinal product which have undergone the consultation under the MDD, company shall submit following documents to MCA (MDCG 2020-12);**  The last opinion of the medicinal products authority under the MDD, as well as a consolidated list of changes, if any, in the following:  • the ancillary substance,  • its manufacturing process,  • the way the substance is incorporated into the device,  • design, manufacturing of the device which could influence the quality, safety or usefulness of the ancillary substance, and/or the parts of the technical documentation related to the above aspects. | √ |

1. **DECLARATIONS**

|  |  |
| --- | --- |
| **Person declares that the information stated in this form and its annexes are correct by signing this form.** | √ |
| **Person declares that,**  **Either there is no other application to any other notified body for the same device- related quality management system before stated in this form and its annexes by signing this form.**  **or**  **there is no other application to any other notified body for the same device- related quality management system as parallel to this application stated in this form and its annexes by signing this form \*\*.**  **or**  **all available inputs and outputs of previous applications/reviews are provided and accepts direct communication with applicable Notified Bodies.**  ***\*\*****The manufacturer may not lodge an application in parallel with another notified body for the same conformity assessment procedure (Article 53- Regulation (EU) 2017/745).* | √ |
| **When the change is detected in the information stated in this form and its annexes, person, who signs this form, approves that agreement terms and the pricing can be changed.** | √ |
| **Person, who signs this form, approves that the application might be rejected as a result of application assessment activities.** | √ |
| **Person, who signs this form, approves that the results of application assessment activities might be informed to competent authorities.** | √ |
| **The person, who signs this form, approves that MCA might contact with competent authority by utilizing company information depending on the result of application assessment activities.** | √ |
| **Company declares that products do not consist of human blood and its derivatives, animal tissue and its derivatives, harmful substances.** | √ |
| **The outsourcing critical suppliers for the complete manufacturing and design processes does not fully outsource these services to another companies.** | √ |
| **The person, who signs this form, approves that obligation to communicate the vigilance notices to the Notified Body.** | √ |
| **The person, who signs this form, undertakes to comply with the requirements of the approved quality system and to maintain it fully and effectively.** | √ |
| **The person, who signs this form accepts that the data obtained from the medical devices at the post-market stage shall carry out the necessary corrective actions and establish a system for this and that this system shall be kept up to date. This commitment shall cover the obligation to inform the Competent Authorities immediately from the moment the manufacturer is informed of the following situations.**  **a) which may or may have led to serious deterioration or death in the health condition of the patient or user;**  **1) The deterioration or deviation of the characteristics and / or performance of the medical device,**  **2) Inadequacies in the instruction manual and label,**  **b) technical and medical reasons which depend on the nature and performance of the medical device, which causes systematic withdrawal of the same type of medical devices from the market by the manufacturer for the reasons specified in (a).** | √ |
| **In re-certification applications; the person, who signs this form accepts that any changes of the original products and any changes data related to, performance, technical, scientific and medical requirements of the original products regarding to regulations, standards, common specifications (those were defined in Annex VII 4.11 of MDR) shall inform to the MCA\*\*\*.**  **\*\*\*The changes in the re-certification application shall be notified and evidence documents shall be submitted with FR.MED.51 Form.** | √ |

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| **Company Representative** | **Name, Surname, Title** | **Signature** | **Date** |
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