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| **IMPORTANT NOTE FOR APPLICANTS**  **The information provided on this form is transmitted directly to the certification department. Any incorrect information submitted may result in the issuance of an invalid document. UDEM Adriatic d.o.o. is not responsible for any consequences arising from incorrect information or failure to meet manufacturer’s obligations. Please ensure that all information is complete, valid and correct, and confirm this before submission.**  **For the necessary documents and information to be submitted by the manufacturer during the application and contractual agreement stages under 2017/745/EU MDR, please review the “UDFRM.04-02 MDR Application Requirements” document which is available on the UDEM Adriatic d.o.o. web site (www.udemadriatic.com).** | | | | | |
| **GENERAL INFORMATION FOR APPLICATION** | | | | | |
| **Application Date** |  | | | | |
| **Full Name of the Company and SRN Number** |  | | | | |
| **Address of the Company**  **(Address of its registered place of business)** |  | | | | |
| **Authorised Representative Name and SRN Number (If applicable)** |  | | | | |
| **Authorised Representative Address (If applicable)** |  | | | | |
| **Activity Area of the Company** |  | | | | |
| **Please define ISO 13485:2016 Scope and Product Groups of the Company** |  | | | | |
| **Tax Office / Tax Number** |  | | | | |
| **Phone No** |  | **Fax No** | |  | |
| **E-mail Address** |  | **Web Site Address** | |  | |
| **Name-Surname and Title of the Top Manager** |  | **Name-Surname of Person Responsible for Regulatory Compliance** | |  | |
| **Name-Surname and Title of the Person who will be communicated (Contact Person)** |  | **Mobile Phone No and E-mail Address of the Contact Person** | |  | |
| **Is the company a SME (small and medium-sized enterprise) as defined in Recommendation 2003/361/EC?** |  | | | | |
| **Accreditation request for ISO 13485:2016** | **(\* Please confirm our accreditation schedules at** [**www.udemadriatic.com**](http://www.udemadriatic.com)**)** | | | | |
| **Standard/Regulation for Service Requested** |  | | **Certification Type Requested** | |  |
| **Design and Development** |  | | | | |
| **Define the clauses excluded according to ISO 13485:2016 quality management system standard** |  | | | | |
| **Please define the product/service realization processes, operations, functions, relationships, technical resources and products in your organization** |  | | | | |
| **(If there is) Other branch office, factory etc. addresses in requested certification scope** | **Branch Office 1** **:**  **Branch Office 1** **:**  **Number of employees** **:**  **Address** **:**  **Branch Office 2** **:**  **Number of employees** **:**  **Address** **:**  **Factory 1** **:**  **Number of employees** **:**  **Address** **:**  **Factory 2** **:**  **Number of employees** **:**  **Address** **:** | | | | |
| **Please explain the reason if you’d like to transfer your certificate/application** |  | | | | |
| **If your company is a part of another Company/Entity, please specify the Company/Entity Name** |  | | | | |
| **The name of the consultancy company if a professional consultancy has been received** |  | | | | |
| **Do you have any withdrawn application with another notified body for the product(s) in this application?**  **Do you have any application/certification refused by any notified body for the product(s) in this application?**  **If yes, please specify the reasons for the withdrawal/refusal decision, related products and notified body information.** | **Reasons for withdrawn/refused**  **applications, information on the**  **products and notified body** **:** | | | | |
| **Do you have a contract signed with any notified body for the same conformity assessment activities within the scope of MDR for the devices specified in the application?** |  | | | | |
| **Has the company been certified by another Notified Body for the products in the application?**  **If yes, please specify the name(s) of the Notified Body(s) and the type(s) of the certificate(s). If the certificate(s) is invalid, please specify the reasons for the invalidation.** | **If YES, please fill in the followings.**    **Name and Number of NB** **:**  **Number of Existing Certificate Valid** **:**  **Validity Date of the Existing Certificate** **:**  **If Certificate is Invalid, Reasons** **:** | | | | |

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| **INFORMATION ABOUT THE COMPANY AND ORGANIZATION STRUCTURE** | | | | | | | | |
|  | **Is your company already certified to ISO 9001:2015, ISO 14001:2015, and OHSAS 18001, and are the related certificates available?** | | | | |  | | |
|  | **For ISO 13485:2016 Medical Devices Quality Management System (MDQMS), please specify the name of the person who has been assigned to the implementation and maintenance of the QMS, and his/her contact information.** | | | | |  | | |
|  | **Please state the “ISO 13485 system operation date”** | | | | |  | | |
|  | **Has the ISO 13485:2016 audit been performed by an independent organization/certification body?**  **If yes, please provide the certificate information, including the certification body name, certificate number, validity period, and certification scope.** | | | | |  | | |
|  | **Number of Personnel** |  | | | **Number of effective personnel**  **Please include management, quality, production, warehouse, R & D, purchasing departments in effective number of employees** | | |  |
|  | **Part Time # of Personnel** | | | **Part Time Shift # of Personnel** | | **Full Time # of Personnel** | **Unqualified # of Personnel** | |
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|  | **What are the company’s processes? Please indicate them all processes.**  **(Management, quality, production, warehouse, R & D, purchasing etc.)** | | | | | | | |
| **Process & # of Personnel Number** | | **Process & # of Personnel Number** | | | **Process & # of Personnel Number** | **Process & # of Personnel Number** | |
| / | | / | | | / | / | |
| **Process & # of Personnel Number** | | **Process & # of Personnel Number** | | | **Process & # of Personnel Number** | **Process & # of Personnel Number** | |
| / | | / | | | / | / | |
|  | **Please indicate if reprocessing is necessary for your device. (if necessary) please explain the reprocessing activity.** | | | | |  | | |
|  | **If there are any locations not covered by the scope of the company’s certification, please provide their addresses and any pertinent details.** | | | | |  | | |
|  | **Please indicate the scope of the products and services offered by your company. Please list your products and provide the corresponding production flow charts.** | | | | |  | | |

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| **INFORMATION ABOUT THE PRODUCTS AND CONFORMITY ASSESSMENT SCOPE** | | |
|  | **Number of applied technical files** |  |
|  | **Technical Characteristics of the Devices** |  |
|  | **MDR Conformity Assessment Route** | **\*Only for Class III custom-made implantable devices.** |
|  | **Is there an implantable device in your application scope?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **For active medical devices;**  **does the device incorporate a Software, or is the device itself a Standalone Software?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **Harmonized Product Standards on the device basis** |  |
|  | **If there are other applicable EU legislation for the products within the scope of the application, please specify these legislations for each device (e.g. 2006/42/EC Machinery Directive, 2014/68/EU Pressure Equipment Directive, 2001/83/EC Medicinal Products Directive, 2011/65/EU Directive (ROSH), 1907/2006/EC Regulation (REACH) etc.).** |  |
|  | **Does the device incorporate a Nanoparticle / Nanomaterial?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **Does the device incorporate as an integral part an in vitro diagnostic medical device?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **Is there any “product or group of products without an intended medical purpose listed in Annex XVI of the MDR” in your application?**  **If yes, please clearly state related device name(s) and its group number in the Annex XVI.** | **If Yes,**  **MDR ANNEX XVI PRODUCT GROUPS:**   1. ***Contact lenses or other items intended to be introduced into or onto the eye.*** 2. ***Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.*** 3. ***Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.*** 4. ***Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty.*** 5. ***High intensity electromagnetic radiation (e.g. infra-red, visible light and ultraviolet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.*** 6. ***Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.*** |
|  | **Is there any “Class III custom-made implantable device” in your application?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **Is there any sterile device in your application?**  **If yes, please clearly state related device name(s) and related sterilization method.** | **If Yes,** |
|  | **Is there any device with measurement function in your application?**  **If yes, please clearly state related device name(s).** | **If Yes,** |
|  | **Is there any orphan device as defined in MDCG 2024-10 guidance in your application?**  **If yes, please clearly state related device name(s) and specify whether there is any Expert Panel Advice on the orphan device status and the clinical data needed for the clinical evaluation.** | **If Yes,** |
|  | **Is there any novel device in your application?**  **If yes, please clearly state related device name(s) and novel features of the device and/or the related clinical procedures.** | **If Yes,** |
|  | **If the devices in your application include any substance/material specified on the right side, please mark the related substance/material and clearly state related device name(s).** | **If Yes:**  **If Yes:**  **If Yes:**  **If Yes:**  **If Yes:** |
|  | **Please mark the processes conducted during production process** |  |
|  | **Please specify whether the following processes are carried out internally or externally. If any process is outsourced, please provide the address of the external provider.** | 1. **Production**     **Firm** **:** **:**  **Address** **:**  **Process** **:**   1. **Sterilization**     **Firm** **:** **:**  **Address** **:**  **Method** **:**   1. **Packaging**     **Firm** **:** **:**  **Address** **:**  **Validation** **:**   1. **Storage**     **Firm** **:** **:**  **Address** **:** |
|  | **Please define critical suppliers/subcontractors with the processes, if any.** | 1. **Critical Supplier/Subcontractor -** **Firm/Address/Process:**      1. **Critical Supplier/Subcontractor -** **Firm/Address/Process:**      1. **Critical Supplier/Subcontractor -** **Firm/Address/Process:** |

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| **PLEASE FILL THE TABLE COMPLETELY FOR THE PRODUCTS WITHIN THE SCOPE OF MDR APPLICATION.** | | | | | | |
| **Technical File Name / No** | **Product Name and Models** | **EMDN Code / BASIC UDI-DI** | **Rule / Class** | **Intended Use and Body Part that the device is in contact with** | **Invasive Device** | **Max. Contact Duration (if invasive)** |
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*\*\** *If you have more than 6 product, please add this page for other products.*

**DECLARATION**

**I have read and commit to comply with “FRM.13 Application Requirements” for ISO 13485:2016 certification requests, and “UDFRM.04-02 MDR Application Requirements” for 2017/745/EU MDR certification requests. Hereby I declare that the above information is valid, complete and correct, I accept the responsibility in case of misinformation or lack of information.**

**I hereby declare and commit that, as of the date of completion of this form, I have not previously made any application to another CONFORMITY ASSESSMENT BODY and/or NOTIFIED BODY for the same products and the associated Quality Management System (QMS) mentioned herein. I declare and commit that I will meet the requirements and maintain the Approved Quality Management System for the products that I have the responsibility to manufacture.**

**I declare and commit that I will provide documents and information to UDEM for the certificate(s) that I received from another notified body for the products that I apply to UDEM, certification dates, surveillances audits, audit results.**

**If any medical device covered by the application incorporates, as an integral part, a substance which may be considered to be a medicinal product within the scope of the 2001/83 EC Directive, if used separately, including a medicinal product derived from human blood or human plasma; I will inform about this situation, and I declare and commit that I will share the all necessary information to evaluate the test results, the usefulness, quality and safety of human blood/plasma derivative or medicinal substance.**

**I declare that animal/human tissues or their derivatives are not used at the medical device manufacture in accordance with the regulations for the use of animal/human tissues.**

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| **On behalf of the Company**  **Full Name-Surname, Signature, Stamp, Date** |  | **UDEM Adriatic d.o.o.**  **Zagreb, Radnicka Cesta 54/R3**  **Tel : + 385 (1) 4819 601**  **info@udemadriatic.com**  **www.udemadriatic.com** |
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