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| **The information given on this form is transmitted directly to the section of the certification. Incorrect information given in the application form may result in the preparation of false document. The information provided is incorrect and / or the company is not responsible for the lack of obligations to live. Make sure the information is correct and confirm.** | | | | | |
| **Application Date** |  | | | | |
| **Full name of the company and SRN Number** |  | | | | |
| **Address of the company** |  | | | | |
| **Authorised Representative Name and SRN Number (If applicable)** |  | | | | |
| **Authorised Representative Address (If applicable):** |  | | | | |
| **Activity Area:** |  | | | | |
| **Please define ISO 13485 Scope and Product Group (In Croatian and in English)** |  | | | | |
| **Tax Office / Tax Number** |  | | | | |
| **Phone No** |  | **Fax No** | |  | |
| **E-mail** |  | **Web Site** | |  | |
| **Name And Title of The Person Who Will Be Communicated** |  | **Person Responsible For Regulatory Compliance** | |  | |
| **Name And Title of The Top Manager** |  | **Mobile Phone No. of The Top Manager** | |  | |
| **Accreditation request for ISO 13485:2016** | **(\* Please confirm our accreditation schedules at** [**www.udemadriatic.com**](http://www.udemadriatic.com)**)** | | | | |
| **Service Requested System Standard** |  | | **Service Requested System Standard** | |  |
| **Design** |  | | | | |
| **Define the clauses excluded according to 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 certification scope** | **Branch Office 1** **:**  **Number of employees** **:**  **Branch Office 2** **:**  **Number of employees** **:** | | | | |
| **Please explain the reason if you’d like to transfer your certificate** |  | | | | |
| **If your company depended another company, Company Name is** |  | | | | |
| **The name of the company if a Professional consultancy has been received** |  | | | | |
| **Do you have any withdrawn application with another notified body? Do you have any application refused by any notified body?** |  | | | | |
| **Is the company certified by another notified Body for the products in the application?** | **Number of NB** **:**  **Number of Existing Certificate Valid** **:**  **Date of the Existing Certificate** **:** g | | | | |

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| **Information About The Company and Organization** | | | | | | | |
| **1.** | **If your company is already ISO 9001:2015, ISO 14001:2015, OHSAS 18001, the system certifications available?** | | | |  | | |
| **2.** | **For Medical Devices Management System (MDQMS) the name of the person who has been assigned to the implementation and maintenance of the profession and what contact information?** | | | |  | | |
| **3.** | **ISO 13485 system operation date** | | | |  | | |
| **4.** | **Is 13485 audit carried out by an independent organization or is there a client / approval / certificate have? The organization, validity, number and the certificate name?** | | | |  | | |
| **5.** | **Type of Audit** | | | |  | | |
| **6.** | **Number of Personnel** |  | | **Number of effective personnel**  **Please include management, quality, production, warehouse, R & D, purchasing departments in effective number of employees** | | |  |
| **7.** | **Part Time # of Personnel** | | **Part Time Shift # of Personnel** | | **Full Time # of Personnel** | **Unqualified # of Personnel** | |
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| **8.** | **What are the company’s processes? Please indicate them. (Management, quality, production, warehouse, R & D, purchasing etc.)** | | | | | | |
|  | **Process & # of Personnel** | | **Process & # of Personnel** | | **Process & # of Personnel** | **Process & # of Personnel** | |
|  | / | | / | | / | / | |
| **9.** | **Please indicate if reprocessing is necessary for your single-use device. (if necessary) please explain the reprocessing activity.** | | | |  | | |
| **10.** | **Outside the scope of activities associated with the company's certification, address (s) if available please provide information about these places.** | | | |  | | |
| **11** | **Please indicate the scope of products and services offered in the company. Please write your products. Please send it to production flow charts.** | | | |  | | |

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| **Information About The Products** | | |
| **1.** | **Number of applied technical files** |  |
| **2** | **Technical Characteristics Of The Devices** |  |
| **3** | **Is It An Implantable Products? (*If there is more than one device, describe it one by one.)*** |  |
| **4** | **For active medical devices; Software?** |  |
| **5** | **Product Harmonized Standards** |  |
| **6** | **Nanoparticle / Nanomaterial** | **If Yes:** |
| **7** | **Does the device incorporate as an integral part an in vitro diagnostic device?** |  |
| **8** | **If the product is an application include the articles as specified in, please mark.**  **(If Yes Please write product name)** | **If Yes:**  **If Yes:**  **If Yes:**  **If Yes:**  **If Yes:** |
| **9** | **Please mark the processes conducted during production process** |  |
| **10** | **Please define the following processes providing externally or internally. If there is any external process please also define the address** | 1. **Production**     **Firm** **:** **:**  **Address** **:**   1. **Sterilization**     **Firm** **:** **:**  **Address** **:**  **Method** **:**   1. **Packaging**     **Firm** **:** **:**  **Address** **:**  **Validation** **:**   1. **Storage**     **Firm** **:** **:**  **Address** **:** |
| **11** | **Please define critical suppliers with the processes, if any** | 1. **Critical Supplier** **Firm/Address/Process :**      1. **Critical Supplier** **Firm/Address/Process :**      1. **Critical Supplier** **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 / Models** | **EMDN / BASIC UDI / UDI-DI** | **Rule / Class** | **Intended Use and body part that the device is in contact with** | **Invasive?** | **Max. Application Time (if invasive)** |
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*\*\** *If you have more than 6 product, please add this page for other products.*

**DECLARATION**

**I read and commit to follow the UDEM Applications Conditions Form for ISO 13485:2016 request FRM.13 and for 2017/745/EU MDR request UDFRM.04-02 MDR application request. Hereby I declare that the above information is valid and correct, I accept the responsibility in case of misinformation or lack of information.**

**I declare and commit that I previously have no application to another CONFORMITY ASSESSMENT BODY and/or NOTIFIED BODY for the products and products QMS mentioned in this form as the date of the completion of the form. I declare and commit that I will meet the requirements and maintain the Approved Quality System in scope 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.**

**I declare and commit that I will share the information of the test results required at practibility, Quality and safety evaluation of human blood or material which is taken into consideration for the intended use of the medical device showing that in case of the medical devices as part of a whole including the human blood or derivative material.**

**I declare that animal tissues are not used at the medical device manufacture in accordance with the regulations for the use of animal tissues)**

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