MEDICAL DEVICES CERTIFICATION APPLICATION FORM

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			
Tel No		**Fax No**	
E-mail		**Web site**	
Name and Title of the person who will be communicated:		**Name of the Management Representative**	
Name and Title of the Top Manager		**Mobile Phone no. of the Top Manager**	
Accreditation request for ISO 13485:2016	☐ **HAA** **(* Please confirm our accreditation schedules at www.udemadriatic.com)**		
Service Requested System Standard:	☐ **ISO 13485:2016*** ☐ **2017/745/EU MDR**	**Service Requested System Standard:**	☐ **Certification** ☐ **Change of scope** ☐ **Reassessment** ☐ **Transfer**
Design:	☐ **(Yes)** ☐ **(Out of scope)**		
Define the clauses excluded according to management system standard:			

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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:	
Please mark the processes conducted during production process	☐ **metal processing** ☐ **plastic processing** ☐ **non-metal mineral processing including glass, ceramics** ☐ **non-metal non-mineral processing including textiles, rubber, leather, paper** ☐ **biotechnology** ☐ **chemical processing** ☐ **production of pharmaceuticals** ☐ **clean rooms and associated controlled environments** ☐ **electronic components including communication devices** ☐ **packaging, including labelling** ☐ **installation, refurbishment** ☐ **reprosessing**
Please define the following processes providing externally or internally. If there is any external process please also define the address.	**1. (Production Site):** **(Internal)** ☐ **(External)** ☐ _____ **2. (Sterilization):** **(Internal)** ☐ **(External)** ☐ **(Firm Name)** _____ **(Address)** _____ **(Method)** _____ **3. (Packaging):** **(Internal)** ☐ **(External)** ☐ **(Firm Name)** _____ **(Address)** _____ **(Validation)** _____ **4. (Storage):** **(Internal)** ☒ **(External)** ☐ **(Firm Name)** _____ **(Address)** _____

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Please define critical suppliers with the processes, if any	**(Critical supplier 1):** **(Address):** **(Process):** **(Critical supplier 2):** **(Address):** **(Process):**
The name of the company if a Professional consultance has been receieved	
Do you have any withdrawn application with another notified body ? Do you have any application refused by any notifed body?	■ **No** ☐ **YES**
Is the company certified by an another Notifed Body for the products in the application	☐ **NO** ■ **YES** **MDD** ☐ **MDR** ☐ **Number of NB:** **Number of Existing Certificate Valid:** **Date of the Existing Certificate:**
For active medical devices; Does it have a software?	■ **YES** ☐ **No**
If the products in application include the articles as specified in, please mark. (Please write product name in the blank)	☐ **(Drug)** ..... ☐ **(Human blood derivative)** ..... ☐ **(Tissues of animal origin)** ..... ☐ **Substances absorbed by or l ocally dispersed in the human body** ..... ☐ **CMR or endocrine-disrupting substances** .....

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PLEASE FILL THE TABLE COMPLETELY FOR CE MARKING APPLICATIONS						
TECHNICAL FILE NAME/NO	**PRODUCT NAME**	**CLASS**	**RULE**	**GMDN CODE or UDI-DI**	**PURPOSE OF USE AND PLACE**	**MAX. APPLICATION TIME IF IT'S INVASIVE**
		None				
		None				
		None				
		None				
		None				
		None				

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***PLEASE WRITE PURPOSE OF USE AND PLACE IN DETAIL**

A)	**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 and the certificate name?**	
5-	**Is it an Implantable product?**	■ **Yes** ☐ **No**
6-	**Technical characteristics of the product**	
7-	**Product Harmonized Standards**	
8-	**Type of Audit**	☐ **ANNEX IX(I)** ☐ **ANNEX IX(II)** ☐ **ANNEX XI(A)**
9-	**Number of personnel**	**Number of effective personnel:** **Please include management, quality, production, warehouse, R & D, purchasing departments in effective number of employees:**
	Part time :	**Unqualified personnel number :**
	Part time (shift) :	**Full time :**
	What are the company's processes?Please indicate them.(management, quality, production, warehouse, R & D, purchasing etc.)	
	Process :	**Personnel number in this process :**
	Process :	**Personnel number in this process :**
	Process :	**Personnel number in this process :**
	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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DECLARATION

1. **I read and committ 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.**

2. **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.**

3. **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.**

4. **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.**

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

Full Name, Signature, Stamp, Date

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