MDR CHANGE NOTIFICATION FORM

MANUFACTURER NAME				
MANUFACTURER SRN				
MANUFACTURER ADDRESS				
CONTACT PERSON (NAME-SURNAME and ROLE)				
CONTACT PERSON TELEPHONE				
CONTACT PERSON E-MAIL				
CHANGE TYPE	***Please select the appropriate option(s) from the followings:***			
	Planned changes for QMS and/or device range covered by QMS		**Planned changes for the approved device(s)**	
	☐	Change of company name	☐	Change of device name / trademark
	☐	Change of company's address / Relocation	☐	Change of the intended purpose of the device (including claims, indications, contra-indications, warnings, target population etc.)
	☐	Change in the legal status of company (including mergers or acquisitions)	☐	Change of the materials / components of the device
	☐	Change of Person Responsible for Regulatory Compliance (PRRC) or other Critical Personnel	☐	Changes of the performance /design specifications of the device
	☐	Change of EU Authorized Representative	☐	Changes in the labelling, packaging, stability, shelf life of the device
	☐	Change in the quality management system structure	☐	Change of software, its operating system and/or algorithms
	☐	Change of the design or manufacturing facilities (including additions or deletions)	☐	Change of the medicinal substance incorporated into device, including its specifications or changes in manufacturing or inspection processes of the substance

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	☐	Change of critical suppliers or subcontractors	☐	Other device changes (*please specify*):
	☐	Changes to the sterilization (process/ cycle/ equipment/ facility)		
	☐	Change in the manufacturing processes		
	☐	New manufacturing line or technology		
	☐	Change in testing or inspection processes		
	☐	Changes to the device range covered by the quality management system (additional or deleted device(s)/device groups/models/accessories)		
	☐	Other QMS changes (*please specify*):		
CHANGE DESCRIPTION *Please briefly describe all planned changes / modifications compared to previous situations*				
REASON AND ORIGIN FOR THE CHANGES / MODIFICATIONS				
DATE / TIMEFRAME OF IMPLEMENTATION FOR PLANNED CHANGE				
CERTIFICATE(S) AFFECTED BY THE CHANGE *Please specify all relevant certificate numbers*				

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DEVICE(S) AFFECTED BY THE CHANGE *Please clearly specify all relevant devices, together with Basic UDI-DIs and other identifying information*	
UPDATED QMS DOCUMENTS AND/OR TECHNICAL DOCUMENTATION DUE TO CHANGE *Please clearly specify related section/part/page of the updated documents/technical documentation*	
NEWLY CREATED DOCUMENTS AS A RESULT OF CHANGE	
NEW/UPDATED VALIDATIONS AND TEST REPORTS *Please attach all new/updated validations and test reports to this notification form as well as other new/updated QMS and/or technical documentation of the planned change*	
<u>IN CASE OF DESIGN/DEVICE CHANGES:</u> A STATEMENT ON THE RELEVANCE TO THE COMPLIANCE WITH GENERAL SAFETY AND PERFORMANCE REQUIREMENTS OF 2017/745/EU MDR **(FOR LEGACY DEVICES ESSENTIAL REQUIREMENTS OF 93/42/EEC MDD)**	

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IMPORTANT NOTES

- *For legacy devices covered by 93/42/EEC MDD certificates, which are subjected to appropriate surveillance referred in Article 120 of 2017/745/EU MDR,* ***significant changes in the device design and intended purpose are not allowed in accordance with Article 120(3c) of MDR.***
  MDCG 2020-3 Rev.1 Guidance shall be taken into account when assessing whether the planned changes are significant.
  If the evaluation by UDEM Adriatic d.o.o. identifies any significant change in design or intended purpose of legacy device, the ***change request WILL NOT be accepted, and all incurred costs will be invoiced.***
- *All related documentation (including new or updated documents) of the planned change has to be submitted to UDEM Adriatic d.o.o. as attached to this notification form.*
- *Depending on the nature of the planned change, on-site audit(s) and/or technical documentation assessment(s) may be carried out by UDEM Adriatic d.o.o. Assessment/audit durations for planned changes are determined by the Project Leader taking into consideration the type and scope of the change.*
- *If planned change requires a new conformity assessment under 2017/745/EU MDR (such as scope extension requests), a new application form (FRM.81 Medical Devices Certification Pre-Application Form) shall be filled by the customer and submitted to UDEM Adriatic d.o.o.*
- *As regards the assessment of the planned changes by UDEM Adriatic d.o.o.,* ***change assessment fees will be charged*** *as specified in the list of standard fees (UDLST.10 List of Standard Fees for Conformity Assessment Activities under MDR), which is publicly available at UDEM Adriatic d.o.o.'s website (www.udemadriatic.com).*

ON BEHALF OF THE MANUFACTURER;
Authorised Personnel Name-Surname
Date - Signature - Seal

This section will be filled by UDEM Adriatic d.o.o

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THE EVALUATION OF THE PLANNED CHANGE NOTIFICATION BY UDEM ADRIATIC D.O.O.	
EVALUATED DOCUMENTS OF CHANGE NOTIFICATION *Please specify all evaluated documents which were submitted by the manufacturer for the change notification*	
DETERMINATION OF CHANGE STATUS	☐ The planned change **IS NOT** a substantial change under MDR that requires submission to and approval by UDEM Adriatic d.o.o. Therefore, **no further action is required of the customer.**
	☐ The planned change **IS** a substantial change under MDR that requires submission to and approval by UDEM Adriatic d.o.o. Therefore, **the following action(s) is/are required:** ☐ **Contract Review and/or Update of the Contract** ☐ **On-Desk QMS Documentation Assessment** ☐ **On-Site Audit** ☐ **On-Desk Technical Documentation Assessment** ☐ **Update/Supplement to EU Certificate(s)** ☐ **Other actions** *(please specify)*:
	☐ **(FOR LEGACY DEVICES)** The planned change **IS** a significant change in the device design and intended purpose in accordance with Article 120(3c) of MDR. **Proposed change CAN NOT be approved by UDEM Adriatic d.o.o. and implemented by the customer.**
	☐ **(FOR LEGACY DEVICES)** The planned change **IS NOT** a significant change in the device design and intended purpose in accordance with Article 120(3c) of MDR. Therefore, **the following action(s) is/are required:** ☐ **Contract Review and/or Update of the Contract** ☐ **On-Desk QMS Documentation Assessment** ☐ **On-Site Audit** ☐ **On-Desk Technical Documentation Assessment** ☐ **Issuance of a Confirmation Letter for Correcting or Complementing Information on Existing MDD Certificates** ☐ **Other actions** *(please specify)*:

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NECESSITY OF A NEW CONFORMITY ASSESSMENT *Please select the appropriate option (yes or no) and explain justification of the decision in detail.* *It should be noted that; if a new conformity assessment is necessary, a new application under the MDR must be submitted by the customer.*	☐ **YES** ☐ **NO** **RELEVANT JUSTIFICATION:**

IF ON-DESK QMS DOCUMENTATION ASSESSMENT WILL BE CARRIED OUT BY UDEM ADRIATIC D.O.O.:

SITE AUDITOR(S)	ASSESSMENT DATE	ASSESSMENT DURATION	DOCUMENTATION TO BE ASSESSED

IF ON-SITE AUDIT WILL BE CARRIED OUT BY UDEM ADRIATIC D.O.O.:

SITE AUDITOR(S)	AUDIT DATE	AUDIT DURATION	AUDITED SITES

IF TECHNICAL DOCUMENTATION ASSESSMENT WILL BE CARRIED OUT BY UDEM ADRIATIC D.O.O.:

PRODUCT REVIEWER(S) AND (IF ANY) CLINICAL EXPERT(S)	ASSESSMENT DATE	ASSESSMENT DURATION	DOCUMENTATION TO BE ASSESSED

TOTAL DURATION OF CHANGE ASSESSMENT	

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CHANGE ASSESSMENT FEE TO BE CHARGED	
FINAL EVALUATION RESULT OF PLANNED CHANGE *Please clearly explain all of the assessment outcomes regarding the planned change notification and specify the final evaluation result.*	

EVALUATED BY THE PROJECT LEADER		
NAME-SURNAME	**DATE**	**SIGNATURE**

INFORMATION ON THE PROJECT LEADER'S ADDITIONAL EVALUATIONS			
If missing information/document was determined during the evaluation or if there is any update as regards assessment of the planned change notification, please clearly indicate additional evaluation dates and results in the following table.			
EVALUATION DATE	**EVALUATION RESULTS**	**REVISIONS ON THE FORM (IF ANY)**	**PROJECT LEADER NAME-SURNAME SIGNATURE**