

MDR QMS AMENDMENT NOTIFICATION FORM



Company Name:		
Address:		
Telephone:		
Mail:		
Scope of the QMS		
Amendments		
Document No:	Related Article of ISO 13485 / MDR	Explanation
Amendment Description		
Name and position of who empowered to sign on behalf of the manufacturer or his authorised representative		
Date		
Signature		

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This section has to be filled by UDEM Adriatic d.o.o

THE EVALUATION OF THE PROJECT LEADER AND SITE AUDITOR(S)

Please write whether additional audits are necessary or not, with the justification of the decision.

Name, Surname of the
Personnel :

Date

Signature

IF NOT AN ADDITIONAL AUDIT IS NECESSARY, THE ASSESSMENT OF THE PLANNED CHANGE:
(Please assess the planned change and write your conclusion about the conformance of QMS to MDR Requirements:

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Name, Surname of the Site Auditor(s) :	
Date of the Assessment	
Signature	