

DEKRA CERTIFICATION GMBH

ATTACHMENT TO APPLICATION FORM C-031-05 MEDICAL DEVICES AND IVD PRODUCTS WITH DETAILS OF ADDITIONAL SITES

NOTES:

- This PDF refers to the application form C-031-05 Medical Devices and IVD Products.
- Please add any information about additional sites and their employees here.
- If the specified number of additional locations is not sufficient, you are welcome to copy the PDF
- as many times as you like and use it for additional sites.
- Please make sure that the sites/subsidiaries are numbered consecutively (A2, A3, etc.).

Please give details below of all further locations and their employees				
Location (A)				
Subsidiary (A)				
Company name				
House no., street				
Further address, if necessary				
Town (and region if necessary)				
ZIP code/Postcode				
Country				
Number of shifts				



Requested Scope	
EN ISO 13485:2016	
+ AC:2018 + A11:2021	
Requested Scope	
ISO 9001:2015	
Requested Scope	
ISO 13485:2016 MDSAP	

	Employees who work between 21 and 40 hours per week on average	Employees who work between 11 and 20 hours per week on average	Employees who work between 1 and 10 hours per week on average	Trainees
Design and development				
Production and varehousing				
Administration, purchasing & miscellaneous				
Quality management, regulatory affairs				

Are some of your services carried out at your customer's premises (projects)?					
No	Yes, as follows:	Number:			

NOTES:

Please attach a copy of your company's current organization chart