DEKRA

DEKRA CERTIFICATION GMBH **APPLICATION FORM MEDICAL AND IVD DEVICES**

Please send two PDF versions of this form to med.certification.de@dekra.com:

1. By “save-as” function
2. With signature

1. Applicant	
Registered company name	
House no., street	
Further address, if necessary	
Town (and region if necessary)	
ZIP code/Postcode	
Country	

2. Please enter your company details below.

Website address	
Email address for general enquiries	
Managing director/owner	Please choose (Salutation) / First name / Last name

Contact person	Please choose (Salutation) / First name / Last name
Contact person's job title	☐ Quality management representative ☐ Executive management ☐ other:
Contact person's email address	
Contact person's phone number	
Contact person's fax number	
Tax code number/VAT ID	

NOTE: Please include a copy of your current trade register excerpt.

3. Please click on the box next to the certification basis according to which you need certification.

- [ ] EN ISO 13485:2016 + AC:2018 + A11:2021
  Please choose

- [ ] ISO 9001:2015 (only possible in combination with one of the displayed certification bases)
  Please choose

- [ ] ISO 13485:2016 TCP, for acceptance in Taiwan
  Please choose

- [ ] ISO 13485:2016 MDSAP (Medical Device Single Audit Program)*
  Please complete the relevant sheets in F-091-57 (see 11. Details of the medical devices which are covered by the certification).
  Please choose

- [ ] (EU) 2017/745 MDR Annex IX, chapter I + III EU Quality Management System
  Please choose

- [ ] (EU) 2017/745 MDR Annex IX, chapter II EU technical documentation assessment certificate
  Please choose

- [ ] (EU) 2017/745 745 MDR Annex XI part A production quality assurance applicable to class IIa devices
  Please choose

- [ ] (EU) 2017/745 MDR Article 120
  Please choose

- [ ] (EU) 2017/745 MDR Article 16
  Please choose

- [ ] (EU) 2017/746 IVDR Annex IX, Chapter I + III EU quality management system for a class A sterile device
  Please choose

- [ ] (EU) 2017/746 IVDR Annex IX, Chapter I + III EU quality management system for class B, C or D devices
  Please choose

- [ ] (EU) 2017/746 IVDR Annex IX, Chapter I + III EU quality management system for class B, C or D devices for self-testing/near-patient testing
  Please choose

- [ ] (EU) 2017/746 IVDR Annex IX, Chapter I + III EU quality management system for a companion diagnostic device (CDx)
  Please choose

* Certification is done through DEKRA Certification B.V., The Netherlands

☐ (EU) 2017/746 IVDR Annex IX, Chapter II EU certificate on the assessment of the technical documentation for a companion diagnostic device (CDx)

Please choose

☐ (EU) 2017/746 IVDR Annex IX, Chapter II EU certificate on the assessment of the technical documentation for a class D device

Please choose

☐ (EU) 2017/746 IVDR Annex IX, Chapter II EU certificate on the assessment of the technical documentation for class B, C, D devices for self-testing/near-patient testing

Please choose

☐ (EU) 2017/746 IVDR Article 16

Please choose

4. Please detail your company's activities below.

What does your company do? In which areas are you active? Please give a short description.	
Which of the following functions does your company carry out? Please click all the relevant boxes.	☐ Design and development of: ☐ Production of: ☐ Distribution of: ☐ Installation of: ☐ Servicing of:

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

5. Do you hold any of the following certificates?		
☐ Yes, as follows:	☐ ISO 9001 ☐ Directive 93/42/EWG ☐ (EU) 2017/745 MDR ☐ ISO 13485:2016 TCP ☐ Other:	☐ EN ISO 13485 ☐ Directive 98/79/EG ☐ (EU) 2017/746 IVDR ☐ ISO 13485:2016 MDSAP
		☐ No

NOTE: Please attach a copy/copies of your certificate(s) and the audit report(s) covering the current certification period.

6. Have you used consultancy services to help you establish the QM System which you are applying for?		
☐ Yes, and their name is:		☐ No

7. Have you used services from other DEKRA companies in the last 3 years? If yes, please specify the type of service.		
☐ Yes, namely:		☐ No

8. Is your production split into different shifts?	
Number of shifts in production:	Do all the shifts carry out the same processes? ☐ Yes ☐ No
	How are the shifts established? ☐ Rolling ☐ Fixed night shift

9. When would you like the certification audit to take place?	

9. Languages - please click the relevant boxes.		
What language is your QM documentation in?	☐ German	☐ English
What language is/are your technical documentation(s) in?	☐ German	☐ English
What language should the audits be conducted in?	☐ German	☐ English
What language should the reports be written in?	☐ German	☐ English

NOTE: The report will be prepared in the same language as the technical documentation. The auditor will not translate any documents. If individual verification documents are not available in the language of the report, these will be accepted in the original language.

NOTE: Documents will only be accepted in German or English.

10. Please give details below of the headquarters and its employees.	
Location/Site (A1)	
Main site/Headquarters (A1)	
Company name	
House no., street	
Town (and region if necessary)	
ZIP code/Postcode	
Country	
Number of shifts	

10a. Please give details below about the number of employees at this location.				
	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 warehousing				
Administration, purchasing & miscellaneous				
Quality management, regulatory affairs				

10b. Are some of your services carried out at your customer's premises (projects)?				
☐ No	☐ Yes, as follows:		Number per year:	

NOTES:
- Please attach a copy of your company's current organization chart.
- For documentation of additional sites, please use form C-031-07 and submit with this application.

11. Details of the medical devices which are covered by the certification.	
See F-091-57 dated (YYYY-MM-DD):	

NOTES:
- In order for us to create your individually tailored offer according to MDR/IVDR we also need you to submit the completed form F-091-57 "Customer data Sheet" (CDS).
- This CDS is the basis for the certification for which you are applying.
- The date entered in section 11 must correspond to the date of revision in the CDS.

THE FOLLOWING DOCUMENTS MUST BE SUBMITTED TOGETHER WITH THIS APPLICATION:

- Extract from the trade register excerpt
- Organization chart
- Data sheet F-091-57 “Customer Data Sheet” (if relevant)
- Current reports/certificates (only for new customers)

12. Confirmation

Date	Name in CAPITAL LETTERS	Digital ID/Signature

RESET FORM