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| Basic Data Organisation MDR | | | | | | | | |
|  | **DQS MED Reference No:** (6-digit) |  | | **Completed on:** | | | | **2020-08-26** |
| **Last saved on:** | | | | **2022-06-10** |
|  | IMPORTANT: Please turn on „Track changes“ when revising this record! 🡪 Shortcut **[Ctrl+Shift+E]** | | | | | | | |
|  | Information about organisation | | | | | | | |
|  | Official name of the organisation  Company name as in official registration (register of commerce, FDA or other) | | | |  | | | |
|  | Official address of the organisation  Complete street address as in official registration (register, FDA or other): **Number and street, place, ZIP/postal code, state/province, country** | | | |  | | | |
|  | Invoicing address | | | |  | | | |
|  | Additional addresses – optional, if required  P. O. Box address, any other addresses | | | |  | | | |
|  | Homepage, telephone, fax  Please provide homepage address and fax number! | | | |  | | | |
|  | VAT-No. | | | |  | | | |
|  | Bank details  Name of the bank, IBAN, BIC | | | |  | | | |
|  | Beneficiary (Trade Register Excerpt) | | | |  | | | |
|  | Contact person in top management\*  e.g. CEO or Managing Director – **Name, position, telephone, fax, e-mail\*** | | | | **Mr. Ms.** |  | | |
|  | Responsible for the management system\*  e.g. Management Representative or Person responsible for regulatory compliance (§15 MDR) – **Name, position, telephone, fax, e-mail\*** | | | | **Mr. Ms.** |  | | |
|  | Contact person in the accounting\*  **Name, position, telephone, fax, e-mail\*** | | | | **Mr. Ms.** |  | | |
|  | Additional contact person\* – optional, if required  **Name, position, telephone, fax, e-mail\*** | | | | **Mr. Ms.** |  | | |
|  | Type and size of business  Activities, main processes and products/services offered on the market, Number of sites and employees/staff | | | |  | | | |
|  | Existing certifications? (not from DQS MED)  If yes, provide copies of certificates! | | | | **Yes (copies attached)   No** | | | |
|  | Legal obligations What law/regulations apply to your management system? | |  | | | | | |
|  | Belonging to larger organisation?  Does your organisation belong to a larger organisation, such as a holding or group of companies? | | **Yes   No** | | **If yes, please provide the larger organisation’s name and your organisation’s role in it 🡪** | |  | |
|  | Use of consulting?\*  Has your organisation used support of an external service provider for its management system?\* | | **Yes   No** | | **If yes, please provide the consultant’s name 🡪** | |  | |

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|  | Information on certification | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  | DQS MED certifications | | | **Please choose the desired or existing DQS MED certifications by entering crosses in the right column 🡫** | | | | | | | | | | | | | | | | | | | | | | | |
|  | Activities (examples) | | | | | | | | | Certification standard or regulation | | | | | | | | | | | | | | | | “X“ |
|  | Medical device manufacturer for the EU/EWR, CE certification 🡫 | | | | | | | | | Regulation (EU) 2017/745 🡫 | | | | | | | | | | | | | | | | 🡫 |
|  | Class I (measuring), Class I (sterile), Class I (reusable) | | | | | | | | | Regulation (EU) 2017/745 Annex IX Chapter I and III | | | | | | | | | | | | | | | |  |
|  | Class I (measuring), Class I (sterile), Class I (reusable) | | | | | | | | | Regulation (EU) 2017/745 Annex XI Part A | | | | | | | | | | | | | | | |  |
|  | Class IIa | | | | | | | | | Regulation (EU) 2017/745 Annex IX Chapter I, III and Section 4 | | | | | | | | | | | | | | | |  |
|  | Class IIa | | | | | | | | | Regulation (EU) 2017/745 Annex XI Part A | | | | | | | | | | | | | | | |  |
|  | Class IIb (without implantable products) | | | | | | | | | Regulation (EU) 2017/745 Annex IX Chapter I, III and Section 4 | | | | | | | | | | | | | | | |  |
|  | Class IIb (implantable products according to the second paragraph of Article 52(4)) | | | | | | | | | Regulation (EU) 2017/745 Annex IX Chapter I, III and Section 4 | | | | | | | | | | | | | | | |  |
|  | Class III | | | | | | | | | Regulation (EU) 2017/745 Annex IX | | | | | | | | | | | | | | | |  |
|  | Products without medical purpose | | | | | | | | | (in accordance with Regulation (EU) 2017/745 Annex XVI) pursuant to Article 1 (2) of Regulation (EU) 2017/745 | | | | | | | | | | | | | | | |  |
|  | Locations of your organisation  All sites involved in the certified activities, belonging to the same QM system. | | | | **Include any operations sites and the head office of your organisation!**  NOTE:  Involved sites that operate a different, independent QM system, can be considered as suppliers and listed in No. 2.3. | | | | | | | | | | | | | | | | | | | | | | |
|  | Nr.  automatic | Nomination  e. g.:  Headquarter, Factory, Warehouse | Adress  Complete street Adress | | **Total count of employees** (full-time equivalent) | **Activities (select by entering „X“)** | | | | | | | | **Technologies used (select by entering „X“)** | | | | | | | | | | | | | |
| **Design and development** | **Production** | **Final testing** | **Storage** | | **Distribution (shipping)** | **Installation** | **Servicing/repair** | **MDT 2001** | **MDT 2002** | **MDT 2003** | **MDT 2004** | **MDT 2005** | **MDT 2006** | **MDT 2007** | **MDT 2008** | **MDT 2009** | **MDT 2010** | **MDT 2011** | **MDT2012** | | |
| **Metal** | **Plastic** | **Non-metallic Mat.** | **Non-metallic /-mineral** | **Biotechnology** | **Chemicals** | **Pharmaceuticals** | **Clean Room** | **Material animal Origin** | **Electronic Components** | **Packaging** | **Installation / Refurbishing** | | |
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|  | Are there critical suppliers/ subcontractors?  Including outsourced production facilities, service providers and any regulatory representatives | | | **Yes  (see below)    No** | | |  | |  | | Examples of activities of critical suppliers / subcontractors: (all of the following activities are considered “critical” when outsourced)  **Design and development, production, population/assembly, packaging, work in clean room, sterilisation, labelling, final testing, finished device provision, involved sister, daughter and mother companies with independent QM systems**  **Attach copies of current certificates of your critical suppliers!** | | | | | | |
|  | Nr.  automatic | Supplier / subcontractor name | Address  complete street address | Is this supplier / subcontractor certified? **If yes, attach certificates!** | **Activities (select by entering „X“)** | | | | | | | | | | | | **Description of what is obtained from this supplier / subcontractor:**   * **product manufactured** * **outsourced processes** * **services provided**   (🡨)EXPLANATION of activities:  **EU- Authorized Representative**– only where applicable for procedures according to Article 11 of regulation2017/745 (MDR) (manufacturer located outside the EU/EWR)  **Person responsible for regulatory compliance** according to Article 15 regulation 2017/745 (MDR) |
| **Critical supplier** | **Critical subcontractor?** | | **Production facility?** | | **Service provider?** | | **Distributor, Art. 14 MDR?** | **Importer, Art. 13 MDR?** | **Other economic operator, Art. 22 MDR** | **EU Authorized Representative, Art. 11 MDR?** | **Responsible person, Art. 15 MDR?\*** |
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|  | | Connection with other QM systems?  Is the QMS subjected to a certification connected to another QMS of your organisation or to an other related company (e.g. QMS of internal or external suppliers)? | | | **Yes**  **No** | **If yes, provide name or related company and describe the connection 🡪** | | |  | | |
|  | | Location of evidence  At what location listed in section 2.2 are QMS related documents and records available? | | | | | | |  | | |
|  | | | | | | | | | | | |
|  | | Information for certification to Regulation (EU) 2017/745 („MDR“) | | | | | | | | | |
|  | | Are you a manufacturer of medical devices in Europe?  Are medical devices of classes III, IIb, IIa, or class I (sterile or with measuring function) placed on the European market under the name of your organisation as manufacturer, or is this planned in near future? | | **Yes   No**  **🡪 continue with 3.2** | | | | EXPLANATION of terms:  **Medical device** – see Regulation (EU) 2017/745 Art. 2 (1)  **Class**– see Regulation (EU) 2017/745 Annex VIII  **Manufacturer**- see Regulation (EU) 2017/745Art. 2 (30) | | | |
|  | | Are you located outside Europe (EU/EEA)? (EU Authorized Representative)  If you, as manufacturer, are located outside the EU/EEA, please provide details on your EU Representative in No. 2.3! | | **Yes 🡪 details in 2.3   No** | | | | **EU Authorized Representative**-see Regulation (EU) 2017/745 Art. 2 (32), Article 11 | | | |
|  | | EUDAMED- registration | Manufacturer | | | | | | | SRN: \_\_\_\_\_\_\_\_\_\_ | |
|  | |  | EU Authorized Representative | | | | | | | SRN:\_\_\_\_\_\_\_\_\_\_ | |
|  | |  | Importer | | | | | | | SRN:\_\_\_\_\_\_\_\_\_\_ | |
|  | |  | Distributor (optional) | | | | | | | SRN:\_\_\_\_\_\_\_\_\_\_ | |
|  | List of Medical Devices (Basic data List of Medical Devices MDR), Spreadsheet “Medical Devices EU”-  **Attached from:** Klicken oder tippen Sie, um ein Datum einzugeben.Click here to select a date | | | | | **Use the DQS-MED form 420\_05\_*Basic Data List of Medical Devices MDR***  Table ***Medical Devices EU*** | | | |
|  | | Location of all evidence  At what locations listed in section 2.2 are all QMS related documents and records available, including product technical documentations according Regulation (EU) 2017/745 Annex II and Annex III? | | | | |  | | | | |

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|  | Substantial changes (not required in case of initial certification request)  **In what cases is this chapter relevant?**   * **You are transferring your certification from another certification body to DQS MED** * **DQS MED asked you to update Basic Data** * **You are planning substantial changes** * **for certification in accordance to Regulation (EU) 2017/745 - before or without delay, for recalls, recommended actions, field corrections, incident reports, etc,** | | | |
|  | Changes in your organisation?  e.g. company name, contact persons, activities, certifications granted by other certification bodies, company size, consultant etc.? | **Yes  No If yes, please explain🡪** |  | |
|  | Changes to your QMS?  e.g. products/services, essential processes, locations, suppliers/subcontractors etc.? | **Yes  No If yes, please explain🡪** |  | |
|  | Regulatory information?  e.g. new or discontinued medical devices, change of economic operators (e.g. EU - Authorized Representative, Critical suppliers or subcontractors etc.)? | **Yes  No  N/A If yes, please explain🡪** |  | |
|  | Vigilance reporting?  Reporting activities according to Art. 87 MDR, performed since your last audit? | **Yes  No   N/A If yes, please explain🡪** | **Serious incidents:** |  |
| **Recalls, advisory notices, field safety corrective actions:** |  |
| **Any other reporting obligations:** |  |
|  | Any significant or substantial changes?  “Significant change” according to Art. 120 MDR and MDCG 2020-3. “Substantial change” according to MDR Annex VII 2.4. and 4.9 | **Yes  No If yes, please detail🡪** | **Significant change:** |  |
| **Substantial change/modification:** |  |
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|  | Additional remarks | | | |
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|  | Approval | | |
|  | **Approved by /revision by:**  Name, Organisation, Position\* | Date | Signature – not required if submitted electronically |
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|  | **Reviewed** by:  Name DQS MED auditor\* | Date | Signature – not required if submitted electronically |
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*\** **Information about the processing of personal data**We use your data (names of contact persons in the company, addresses, telephone numbers, e-mail addresses) according to article 6 1b) DSGVO for the fulfilment of contracts (certification services) or for the performance of contractual actions (e.g. creation of offers), which take place on request of concerned persons.  
  
For the performance of the order, it is necessary to store the data of the client as well as the relevant legal accreditation information of the company, which are mandatory for the order processing. Contact data is especially needed for the planning of certification procedures and the communication between you and us for the fulfilment of the order. The storage of data and the deletion taking effect are regulated by the legal retention periods.  
  
We are obliged to protect received data and information in paper form and digitally by means of all necessary provisions of organizational and technical kind within the meaning of article 32 DSGVO, so that these are protected against unauthorized processing and use; especially disclosure, change, access and deletion. We do not disclose data and information that becomes known from the fulfilment of the order, unless we have your explicit permission or the contractual relationship relates precisely to these activities (e.g. publication of certifications, inspection of certification documents by the accreditation bodies, approval authorities and authorities).  
  
The inclusion of third parties, as well as the transmission of data and information to the same, which are used by DQS MED for the fulfilment of the contract (e.g. auditors, DQS offices, authorities, accreditation and approval bodies), and those who need these data for the fulfilment of the contract, only takes place, when DQS MED has effectively imposed the same obligations to these third parties. An exception forms a possible necessary disclosure of data to superordinate authorities and approved bodies on basis of article 49 paragraph 1 b) DSGVO, on whose actions we do not have influence. Insofar a risk remains for which DQS MED excludes a liability in the event of damage.  
  
In our general certification and accreditation rules, we have determined specific provisions, which also concern the handling of information and data. This document, in the current valid version, is a binding part of the contract between our customers and us.

You have the following rights with us regarding the person-related data concerning you:

* Right to information about your stored person-related data (Art. 15 DSGVO)
* Right to correction, if the stored data concerning you is faulty, obsolete or otherwise incorrect (Art. 16 DSGVO)
* Right to deletion, if the storage is inadmissible, the purpose of processing fulfilled and therefore the storage no longer necessary or you have withdrawn a given consent for the processing of certain person-related data (Art. 17 DSGVO)
* Right to restriction of processing, if one of the conditions specified in article 18, paragraph 1 a) to D) DSGVO is given (Art. 18 DSGVO)
* Right to transfer the provided person-related data concerning you (Art. 20 DSGVO)
* Right to withdrawal of a given consent (Art. 21 DSGVO), whereby the withdrawal does not affect the legality of the processing previously carried out on basis of the consent (Art. 7 Abs. 3 DSGVO) and
* Right to complaint to a supervisory authority (Art. 77 DSGVO)

We would like to point out, that we need your person-related data for the order fulfillment as mentioned above. If you do not agree or no longer agree with that, your certification order cannot be processed or no longer processed.

Responsible person in the sense of the legal data protection regulations for the processing of your person-related data is: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt, Germany, [www.dqsglobal.com](http://www.dqsglobal.com), telephone number +49 (0) 69 95427-300.

Our data protection officer is at your disposal in case of questions regarding the processing of your person-related data under: DQS Medizinprodukte GmbH, data protection officer, August-Schanz-Straße 21, 60433 Frankfurt, Germany or [datenschutz@dqs-med.de](mailto:datenschutz@dqs-med.de).