Process Steps for Applications under VO 2017/745 MDR

Step 1: Customer downloads and completes Basic Data Forms and forward those to

Vertrieb@dqs-med.de (for new customers, without DQS-Med identifier)
zuständigen customer service (for existing costomers)

a.) Basic Data Organisation:420_04e

b.) Basis Data Product: 420_05e

!!Please list here only those products to be covered by the initial certification!!
!! For class IIb- Products enter the corresponding CND category (Level 4)!!

Step 2: Customer receives Quotation / Application Forms (1 for any Technical File per Risk class / product gruop)

Step 3: Customer accepts quotation and sends fully completed an officially signed Application Forms to Customer Service

Step 4: DQS-Med checks applications and approves assessment procedure
Detailed scheduling for Technical File Review and QMS-Audit Steps 1 and 2

Assessor Identification
Registration of the Product category
Informs Customer und asks for timely Technical File Upload
Releases Upfront payment invoice

Step 5: Customer transfers Upfront payment and uploads Technical File

Step 6: Assessor performs Technical File Review and issues Report (with action plan(s), if applicable)
DQS-Med issues report, reviews adequacy of scheduling for Stage 1 audit and postpones, if applicable

Step 7: Stage 1 Audit performed
DQS-Med issues report, reviews adequacy of scheduling for Stage 2 audit and postpones, if applicable

Step 8: Stage 2 Audit performed
DQS-Med issues Report (with action plan(s), if applicable)
Certification proposal

Step 9: DQS-Med synchronizes action plans Product / Quality-Management-System
Scheduling of Review and Certification Board Meeting

Step 10: DQS-Med performs Review and Certification Board Meeting
Uploads certificate
Performs DIMDI-Notification (EUDAMED)
Issues Final Invoicing

Step 11: Customer transfers final payment
Start of Surveillance Activities
- Annual Surveillance Audit
- Annual Review of the Technical Files
- Review from PSUR and SSCP
- Unannnounced Audits
- Audits of critical Suppliers / Subcontractors (if applicable)