

Product Group-Specific Shared Documents



MDR | IVDR
SOFORTHILFE BW

Overview Product Group-Specific Shared Documents

In order to help the medical technology sector in Baden-Wuerttemberg implement the Medical Device Regulation (MDR) the Ministry of Economic Affairs, Labour and Housing Baden-Wuerttemberg made funds available for a MDR & IVDR Fast-Track Support BW programme (“MDR & IVDR Soforthilfe BW”). In the period 2019 to 2021 the programme’s five measures are aimed at saving time and resources for the companies affected (for more information, please visit www.bio-pro.de/en/projects/mdr-ivdr-fast-track-support-bw). This includes, inter alia, developing guide-lines on specific issues and sharing newly acquired information at events. In addition, access to clinical trial centres will be facilitated to help companies that are required to conduct clinical trials due to MDR. BIOPRO Baden-Wuerttemberg GmbH is coordinating the MDR & IVDR Fast-Track Support BW.

Within the measure “Product Group-Specific Shared Documents” company consortia develop basic documents for individual medical device groups, which can be used as a basis for creating individual certification documents. Interested companies can purchase the jointly prepared basic documents from the respective moderating organization. The fee is maximum 1,000 Euro (incl. VAT) for companies in Baden-Wuerttemberg and 1,785 Euro (incl. VAT) for companies located outside Baden-Wuerttemberg.

Product Groups with available basic documents in English:

Biopsy instruments

Document: Literature review
Moderator: MedicalMountains GmbH

Dental Instruments

Document: Literature review
Moderator: MedicalMountains GmbH

Electrocoagulation

Document: Literature review & Literature review
(Monopolar and Bipolar HF Generators)
Moderator: MedicalMountains GmbH

Flexible Endoscopes

Document: Literature review & Literature review
(Polypectomy Snare Devices)
Moderator: MedicalMountains GmbH

Instruments for the surgical suture

Document: Literature review
Moderator: MedicalMountains GmbH

Light Sources and Light Cables for Endoscopes

Document: Literature review
Moderator: MedicalMountains GmbH

Measurement devices

Document: Literature review
Moderator: MedicalMountains GmbH

Mechanical surgical saws

Document: Literature review
Moderator: MedicalMountains GmbH

Medical Devices Artery Clamps

Document: Literature review & Clinical Investigation Plan
& Investigator's Brochure
Moderator: MedicalMountains GmbH

Medical Devices for Insufflation

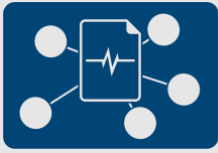
Document: Literature review
Moderator: MedicalMountains GmbH

Coordinated by:



Funded by:





Product Group-Specific Shared Documents



MDR | IVDR
SOFORTHILFE BW

Medical Devices for Intubation

Document: Literature review

Moderator: MedicalMountains GmbH

Medical Devices Transcutaneous/Endovascular Guide Wires

Document: Literature review

Moderator: MedicalMountains GmbH

Medical Devices Vessel Clips

Document: Literature review

Moderator: MedicalMountains GmbH

Medical Suction Devices

Document: Literature review

Moderator: MedicalMountains GmbH

Optotype Devices

Document: Literature review

Moderator: MedicalMountains GmbH

Osteosynthesis (internal / external fixators)

Documents: Literature review Internal
Fixators / External Fixators)

Moderator: MedicalMountains GmbH

Penetrating surgical instruments

Document: Literature review

Moderator: MedicalMountains GmbH

Probes, Dilators, Bougies

Document: Literature review

Moderator: MedicalMountains GmbH

Punching and drilling surgical instruments

Document: Literature review

Moderator: MedicalMountains GmbH

Rigid & Semi-Rigid Endoscopes

Document: Literature review & Literature review
(Endoscopic Guidewire Devices)

Moderator: MedicalMountains GmbH

Sphygmomanometer

Documents: State of the art (GSPR) & implementation
recommendation OEM/PLM

Moderator: NET AG system integration

Sterilization Containers

Document: Literature review

Moderator: MedicalMountains GmbH

Surgical cutting forceps

Document: Literature review

Moderator: MedicalMountains GmbH

Surgical instruments for cutting and ablating of bone

Document: Literature review

Moderator: MedicalMountains GmbH

Surgical instruments for scraping

Document: Literature review

Moderator: MedicalMountains GmbH

Surgical screwdrivers and allen keys

Document: Literature review

Moderator: MedicalMountains GmbH

Wound Dressing

Document: Clinical Evaluation Report (CER), Risk Analysis

Moderator: Allianz faserbasierte Werkstoffe Baden-
Württemberg e.V. (AFBW)

Coordinated by:



Funded by:

