MedicalMountains
SUPPORT IMPLEMENTATION

Support documents for implementation of regulatory requirements

About MedicalMountains GmbH in Tuttlingen, Germany

MedicalMountains GmbH networks and supports all stakeholders within the field of medical technology. It promotes dialogue, unites areas of strength and creates platforms for exchange. Systematic, strategic coordination enables cooperation and creates synergies: Cooperation with regional, national and international partners allows especially small and medium-size companies to achieve significant advances in knowledge and technology.

MedicalMountains Support

MedicalMountains GmbH proactively supports medical technology companies with implementing regulatory requirements. The offerings create time, personnel and financial relief while boosting confidence with respect to regulatory parameters.

The support services are tailored to the requirements of medical technology companies and continously developed.

Content

PASSIVE MEMBERSHIP

Publications of the EU-MDR ExpertTable

In 2018, the MDR ExpertTable began practical implementation of the EU-MDR. Its taskforce, a fixed operative core team, is composed of specialists from large and medium-size medical technology companies. Different key topics of the EU-MDR are addressed in monthly meetings to ensure timely and proper implementation by offering pragmatic instructions, templates and orientational guidelines.

All medical technology companies whose products are subject to the MDR 2017/745 can profit as passive members from the full range of expertise offered by the ExpertTable. MedicalMountains would be glad to receive your questions and applications for passive membership by email.

Publications in 2018/19/20:

- Legally reviewed master-quality assurance agreement in German and English
- Legally reviewed master NDA to supplement the master-quality assurance agreement in German and English
- Legally reviewed specialized trade agreement in German and English
- Master table for structuring the technical documentation based on the EU-MDR
- Information on product group formation / Guideline for intended use
- Information on the declaration of conformity according to the EU-MDR
- Guideline for post market surveillance
- UDI guideline
- Guideline for clinical evaluation
- Glossary of terms
- Other pending publications

Investment:
The fee for passive membership is €3.000 (plus VAT).
This includes all publication released in 2018, 2019 and 2020.

GUIDELINES

Small and medium-size company guidelines for standardized surgical instrument cleaning

The guideline developed within the project CleanMed assists small and medium-size companies in setting up their own suitable process for cleaning validation and gaining security of action and argumentation concerning regulation authorities and Notified Bodies. The guideline serves as an orientation tool and/or benchmark for companies. The guideline is structured chronologically in a modular system and guides you through six process steps.
If users wish to set up a process for typical surgical instruments, they can additionally acquire CleanMed worst-case test specimen that were specially developed for the project. The geometric properties of the CleanMed test specimen are tailored to exemplify the maximum challenges posed by typical surgical instruments to the cleaning process.

Investment:
>> Complete package with test specimen
1 set of printed guideline, 1 box with 3 fully cleaned, welded test specimen, 1 USB stick with additional documentation
Price: €1.200 (plus VAT)
>> Guideline without test specimen
1 printed set of guidelines, 1 USB stick with supplementary documentation
Price: €600 (plus VAT)

Guideline for manufacturers' validation of the reprocessing of reusable medical devices

This guideline offers a procedure for small and medium-size businesses. They can be used as a basis for their own validation of reprocessing.
All medical technology companies whose products are subject to the EU-MDR can order this guideline now (currently in preparation).

Investment:
The package costs €320 (plus VAT). Passive members of the MedicalMountains EU-MDR ExpertTable are offered an additional 20% discount.

CLINICAL LITERATURE EVALUATIONS

MedicalMountains GmbH offers joint reports of clinical literature for a range of product groups as a basis for clinical evaluations written by professional service providers. All medical technology companies whose products are subject to MDR 2017/745 can order these prepared literature reports from MedicalMountains GmbH.

Existing literature reports:

- Cutting instruments: €1.450 (plus VAT)
- Grasping instruments: €1.658 (plus VAT)
- Retracting instruments: €1.450 (plus VAT)

Other literature reports for specific product groups are being coordinated by MedicalMountains GmbH as part of BIOPRO Baden-Württemberg's MDR emergency aid programme, which is funded by the Ministry of Economic Affairs, Labour and Housing of Baden-Württemberg.

Existing literature reports as part of the Baden-Württemberg MDR emergency aid programme:

- L01: Abrasive instruments for hard tissue and bone, Class Ir
- L02: Scraping and rasping instruments for soft tissue, Class Ir
- L03: Mechanical surgical saws, Class Ir
- L04: Penetrating and guiding instruments for soft tissue, Class Ir
- L05: Probing instruments
- L06: Punching and drilling instruments for hard tissue and bone, Class Ir
- L07: Flexible endoscopes
- L08: Light sources and light guides as accessory medical devices for endoscopy
- L09: Rigid endoscopes with and without lens systems
- L10: Medical Devices for electrocoagulation
- L12: Dental instruments
- L15: Instruments for surgical suture
- L16: Measuring devices
- L17: Surgical screwdrivers and allen keys
- L18: Biopsy instruments
- L19: Surgical cutting forceps
- L21: Artery clamps
- L22: Sterilization containers

Investment:
Companies can acquire the literature reports for €1.750 (incl. VAT).

CLINICAL LITERATURE EVALUATIONS

Literature reports currently in preparation:

- L29: Osteosyntheses
- L39: Retrieval devices
- L31: Suction systems

Investment:
Companies can acquire the literature reports for €1.750 (inkl. VAT) after completion.

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