DITABIS

Your first choice for product certification of conformity

Certifications

DITABIS supports your certification process

Accreditation specialist for laboratory and medical equipment

DITABIS offers support in issues of **product accreditation** and **product certification** (laboratory and medical equipment/IVD). DITABIS adopts internationally approved standards and respects the appropriate requirements. Very often the certification of a product is key to open regulated markets. The number of regulations in Europe increase constantly and nearly all products are covered by statutory provisions. We assist you on these issues.

Furthermore DITABIS is developing and producing medical instruments and has the **practical experience** in certifications.

The **first placing in the market** of medical equipment is covered by extensive regulatory requirements, and a **new edition** or **modification of standards** demand reassessment and possible adjustment of safety checks to obtaining certification of conformity.

- CE Conformity
- Risk Management
- CB Report
- EMC tests
- US FDA certification
- Medical Technology

Product Accreditation and Product Certification

CE Conformity

First Marketers bear responsibility that requirements regarding Medical Devices Act (EU directive medical-technical products MDD 93/42/EEC) and In-vitro-diagnostic medical devices (EU directive 98/79/EG are met and products are labelled with a CE mark. DITABIS assists you in complying with these standards.

The services of DITABIS include:

- Assistance in compiling and verifying of technical documentation regarding CE conformity
- Assistance in compiling and checking of a design dossier
- Verification of essential requirements
- Product classification and identification of applicable standards for medical products
- Review of product authentication and packaging

Risk Management

Risk management consists of established processes in order to eliminate or reduce risks by means of conceptual and design measures. DITABIS takes care that requirements regarding risk management in accordance with DIN ISA EN 14791 are met during the entire life cycle of the product, from development through application and disposal.

CB Report

DITABIS offers assistance and technical support with CB certification and with obtaining the CB report and the CB certificate according to a harmonized standard such as IEC 61010, IEC 60950, IEC 60065, IEC 60601 and others. A CB certification facilitates international trade with electrotechnical products and international authorisation procedures and secures compliance with applicable requirements.

EMC Tests

Tests of the electromagnetic compatibility (EMC) of your laboratory and medical equipment assures compliance with limits regarding emission and immunity. DITABIS assists with experience and technical support regarding the elimination of interferences of your laboratory and medical products.

US FDA Certification

You require assistance with international regulatory questions, e.g. the US market? DITABIS offers services in the framework of an investigation and categorizes essential FDA requirements, be it laser safety and laser radiation protection or the filling-out of extensive product reports, we support your efforts.

Talk to us, your first choice for product certification of conformity:

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