GreenSoft
TECHNOLOGY, INC.

Your Partner in Compliance

EU MEDICAL DEVICES REGULATION

Compliance Data Services for the EU MDR

Understanding the EU Medical Devices Regulation Requirements

In May 2017, the European Commission published the **Medical Devices Regulation (MDR).** The regulation became mandatory for medical device producers as of **May 26, 2020**.

The **EU MDR** replaces the previous Medical Device Directive (EU MDD) and the Active Implantable Medical Device Directive.

The **EU MDR** changes how medical devices are defined, how devices are classified for risk, and creates a new labeling system. The regulation also includes certain substance content requirements.

Under the new **EU MDR**, medical devices cannot contain substances classified as carcinogenic, mutagenic, or toxic for reproduction (CMR 1A/1B) or endocrine-disrupting substances (EDS) in amounts over 0.1% w/w without justification. The use of latex, as well as substances of human or animal origin, must also be declared if present.

Some of the largest Medical Device manufacturers in the world use GreenSoft's EU MDR Solution

"Excellent support. Very knowledgeable in the field of compliance. Our process is highly complex, and GreenSoft has done an excellent job of assisting in finding work arounds for most all issues."

–

BD Biosciences
Senior Quality Engineer

EU MEDICAL DEVICES REGULATION

Simplifying Substance Data Collection with GreenSoft's EU MDR Solution

GreenSoft Technology's **EU MDR Data Services** solution provides you with the substance data you need to enable your product to be submitted to the UDI database and evaluated by a notified body for approval, while freeing up your time to focus on other elements of the product approval process.

As part of our **EU MDR Data Services**, we will collect substance data from your suppliers on your behalf, and check it against the list of applicable CMR 1A/1B and endocrine-disrupting substances addressed under the **EU MDR**, using our powerful, purpose-built **GreenData Manager** compliance software.

We leverage the **Full Material Declaration (FMD)** data in our **Component Database** to cut down on supply chain collection time. And we can also help with **EU RoHS**, **EU REACH SVHC**, and other global regulations.

Plus, we will track the regulations that you are complying with for **updates and new substance additions**, and alert you when there are changes, to always ensure that you are showing up-to-date compliance.

We can even collect information on the presence of animal and human derived materials, as well as latex, as required by the **EU MDR**. Contact us today to learn more and get started.

GreenSoft TECHNOLOGY, INC.

IPC Member

bsi ISO/IEC 27001 Information Security Management CERTIFIED

ISO 9001:2015 Certified

AIAG member

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