GreenSoft Technology, Inc. | Compliance is a moving target. We make it easy.

EU MDR

Compliance Data Services for the EU Medical Devices Regulation

Compliance with EU MDR Becomes Mandatory in May 2020

European Commission

Medical Device Regulation (EU MDR)

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

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

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.

Contact us to learn more:
+1-323-254-5961
info@greensofttech.com

Corporate Headquarters
North America/Europe
GreenSoft Technology, Inc.
155 S. El Molino, Suite 100
Pasadena, CA 91101 USA
Tel: (323) 254-5961
info@greensofttech.com

Asia/China/Taiwan/Japan
Jon Wu
Tel: +886-920-618-568
jwu@greensofttech.com

Israel
Rokah Technologies
Tel: +972-3-9360688
reuven@rokah-technologies.com

ISO 9001:2015 Certified

Responsible Minerals Initiative VENDOR MEMBER

SMTA CORPORATE MEMBER

www.greensofttech.com

Get Help With Substance Data

Our **EU MDR Data Services** provide 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 lists 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 already in our component database to cut down on collection time. And we can help with **EU RoHS**, **EU REACH SVHC**, and other global regulations.

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

GreenSoft Technology: A Trusted Partner

At GreenSoft, we have over 14 years of experience in managing compliance data.

We currently work with many **medical device manufacturers** of all sizes.

We have a broad range of expertise in active and passive components, electrical and mechanical parts, packing and printing materials, and raw materials including organic or non-organic chemicals.

GreenSoft has relationships with over 31,000 suppliers worldwide and is **ISO 9001:2015 certified**.

> **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

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