



# EU MDR

## Compliance Data Services for the EU Medical Devices Regulation

### Compliance with EU MDR Becomes Mandatory in May 2020



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

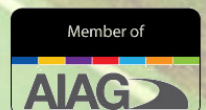
Rokah Technologies  
Tel: +972-3-9360688  
reuven@rokah-technologies.com

#### Finland/Sweden/Norway

RoHS Management Oy  
Tel: +358-44-981-2787  
sales\_europe@rohsmanagement.com



[www.greensofttech.com](http://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 15 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 37,000 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

Contact us to learn more:  
**+1-323-254-5961 or [info@greensofttech.com](mailto:info@greensofttech.com)**

[www.greensofttech.com](http://www.greensofttech.com)

**GreenSoft**  
Technology, Inc.