Barco medical products & the Medical Device Regulation

Our full medical product line is now compliant with the new European MDR regulation. MDR stands for Medical Device Regulation and replaces the Medical Device Directive (MDD), which was in place since 1993. The new MDR is a European law with stricter requirements for any type of medical device available on the European market. At its core is guaranteeing the safety of medical devices used throughout patients' treatment processes.

Class IIa for our diagnostic products

Following products are now certified as Class IIa, because they provide decisive information for diagnosis, influence the displays' medical purpose or alter the representation of medical images:

- Our diagnostic displays for radiology, breast imaging, digital pathology & dentistry
- QAWeb Enterprise
- Intuitive Workflow Tools

That means that our product information is reviewed and cleared by independent medical and technical experts, and this will be audited yearly. In other words, we ensure diagnostic confidence and peace of mind for users

MDR Class IIa Ensuring diagnostic confidence

BARCO

FAQ

Does anything change for me as a user of Barco medical products?

You can keep working with your Barco display as before. Our products have not changed, but their regulatory process has become stricter, with patient safety at its core. The certificate for Barco means that our medical products comply with all legal requirements to be allowed to be sold in Europe.

Does anything change for me as a Barco partner, distributor or reseller?

The full responsibility for MDR compliance of our products lies with us. For our Class IIa products, it is supervised by the notified body TÜV SÜD Product Service GmbH.

For distributors, any medical devices that you place on the market yourself must also be in line with the EU MDR. Want to know more? Check out our training module on distributor responsibilities.

What do the different classes mean?

Depending on the potential patient risks associated with medical devices, they must be categorized in one of four classes. The higher the class, the stricter the requirements laid out in the EU MDR. The MDR lists a series of rules to help manufacturers correctly define the right class for their products.

Our surgical and clinical review displays are Class I medical devices, which means that they pose lesser risk to patients. Our diagnostic displays, QAWeb Enterprise and Intuitive Workflow Tools are certified as Class IIa, because of their purpose for supporting decisive information for diagnosis.

Can I also use a lower class display for diagnostic use?

You are free to choose what medical devices you want to use. However, our regulatory team studied the legislation and classification rules extensively. For diagnostic procedures, our assessment is that products should be class IIa. When choosing Barco, you can be confident that you'll be working with state of the art diagnostic products, confirmed through the yearly notified body review. Note: it is the manufacturer's responsibility to place their products in the correct class.

How does this work for your software solutions?

Just like our diagnostic displays, QAWeb Enterprise and Intuitive Workflow Tools are Class IIa products. QAWeb Enterprise is quality assurance software and considered an accessory to diagnostic displays. The Intuitive Workflow Tools provide information that is used to take decisions with diagnosis.

I'm still working with a display bought under the old Medical Device Directive. Is this a disadvantage for me?

You may keep using your product during its full lifetime, they have not changed. All products placed on the market under a valid MDD certificate may remain on the market. We will also keep supporting any products sold under MDD.

Does MDR have an impact on export procedures?

No. Many non-European countries take the European legislation as guideline or requirement. However, this is mostly applicable to what these countries allow to be sold on their markets. Import or export procedures will normally remain as they were before MDR.

Barco has diagnostic displays as class I and class IIa – How can we see the difference?

All Barco diagnostic displays are classified as class IIa. We do have class I products, with different intended purposes linked to surgical and clinical review.