Master the new MDR regulation

Webinar

16th of May 2023

Introducing the Barco webinar hosts

Katrien Cardoen
Healthcare Compliance Director

Joerg Herrmann
Sales Director EMEA
Diagnostic Imaging

Julie Vandecandelaere
Regulatory Officer

Pushing the world forward through innovation

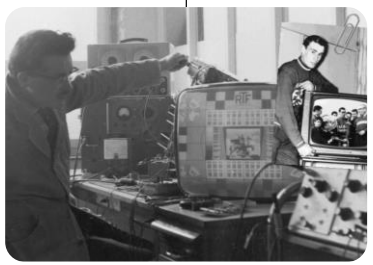
1930s

1950s

1980s

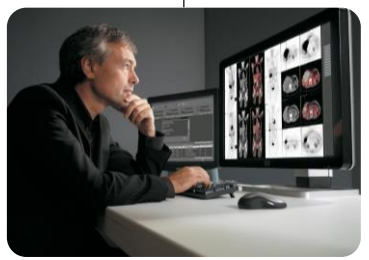
2010s

1940s



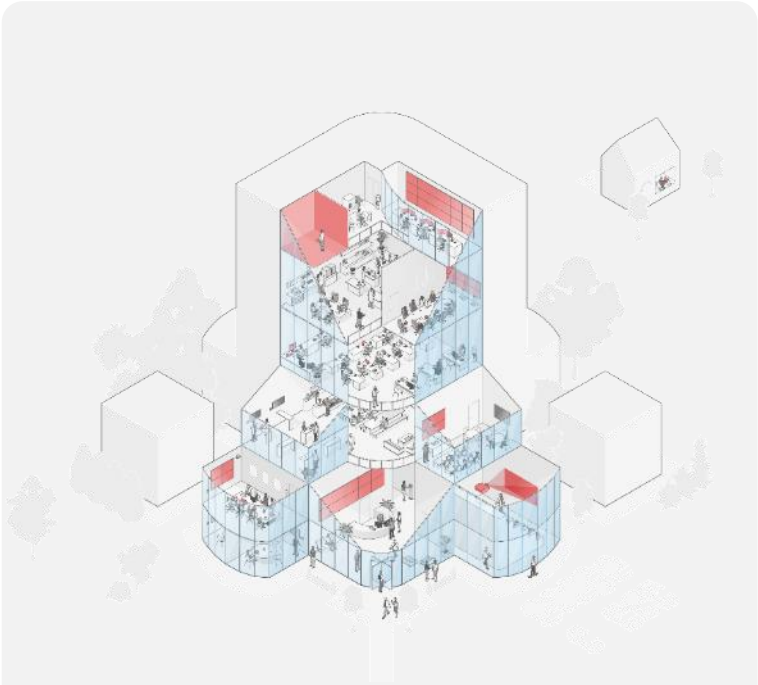
1960s

2000

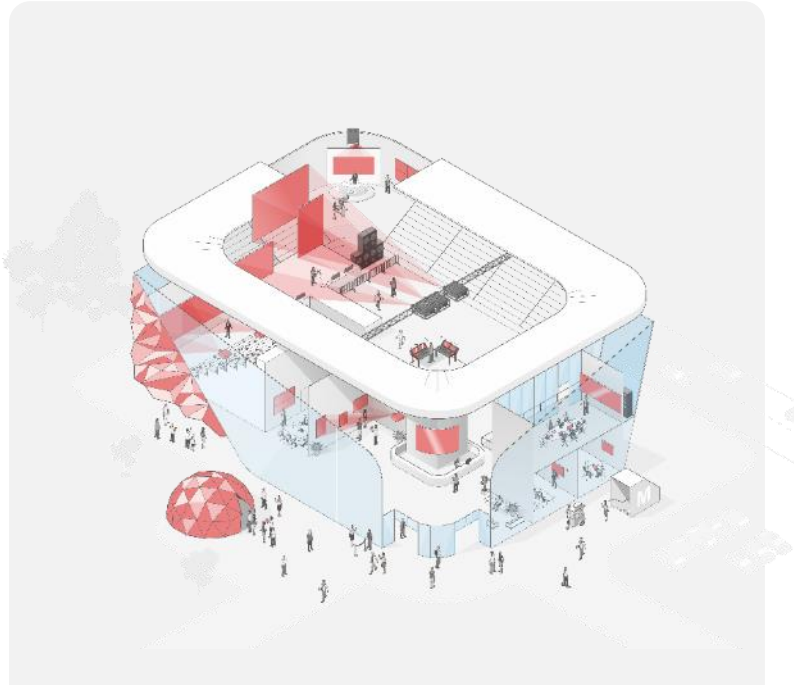


2020s

We are closer to you than you think



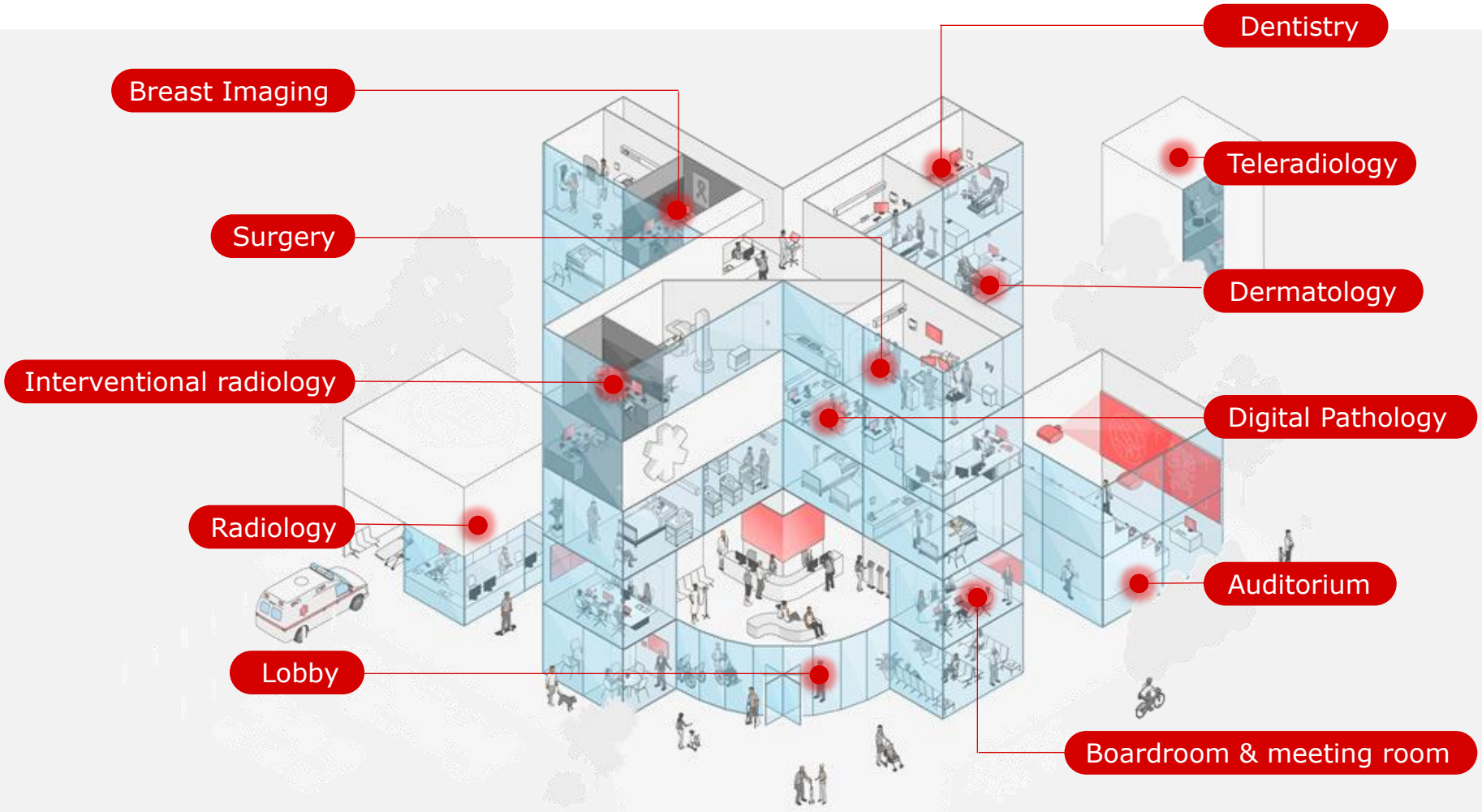
Enterprise



Entertainment

Healthcare

Enabling quality care for more people



Poll 1

Do you know what has changed from MDD to MDR?

Answer Poll 1

- Applicable and binding in all EU member states
- No grandfathering
- Applies to all economic operators
- Life-cycle approach
- Updated classification rules

- New guidance documents
- Increased evidence of compliance
- Traceability
- Increased focus on feedback loops
- State of the Art

Answer Poll 1

- ✓ Applicable and binding in all EU member states
- ✓ No grandfathering
- ✓ Applies to all economic operators
- ✓ Life-cycle approach
- ✓ Updated classification rules
- ✓ New guidance documents
- ✓ Increased evidence of compliance
- ✓ Traceability
- ✓ Increased focus on feedback loops
- ✓ State of the Art

EU Medical Device Regulation 2017/745

Increasing patient safety through transparency, documentation and scientific evidence

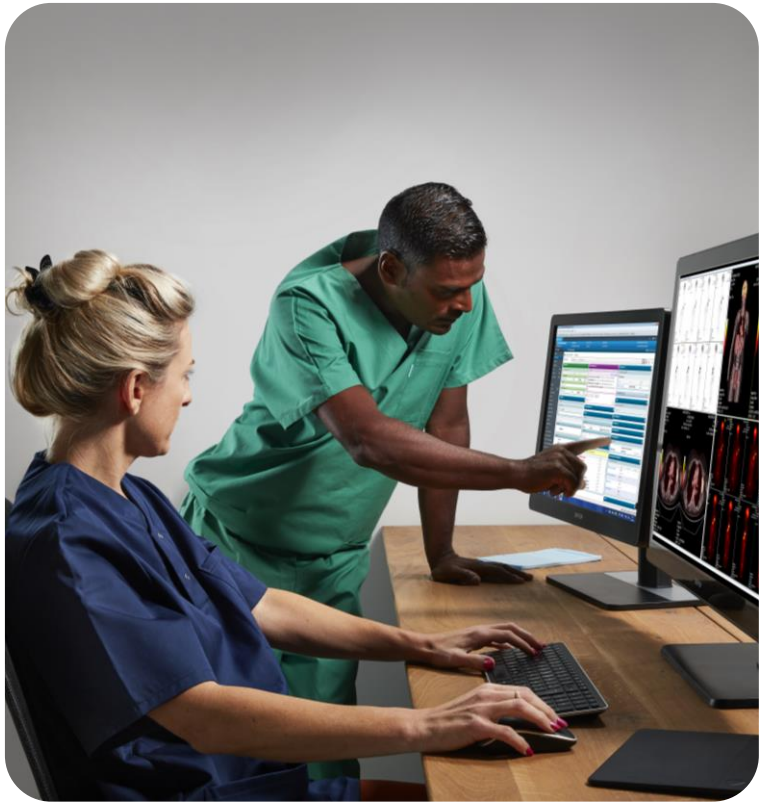
Why a new regulation?

- Several scandals showed that the EU directive did not protect the patient!
- **New technologies** could not be adequately addressed

MDD developed since 1993 is no longer meeting the requirements of a changing world

2017 the EU MDR was issued

- **A state-of-the-art regulation:** impacting all Medical Devices placed on the market in EU
- Barco started the works to **transition** of all products **to MDR requirements**



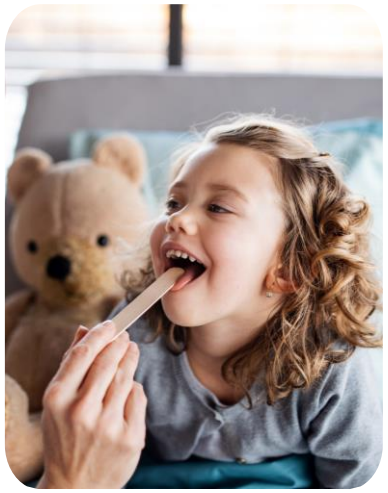
Impact on the EU market

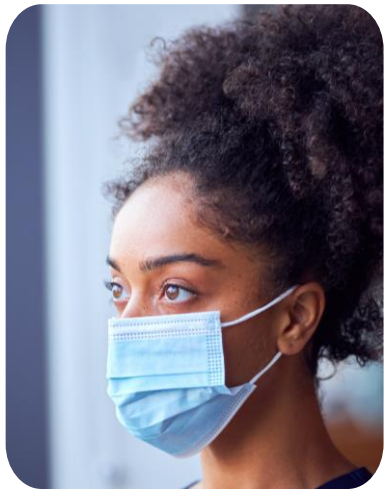
There are more than

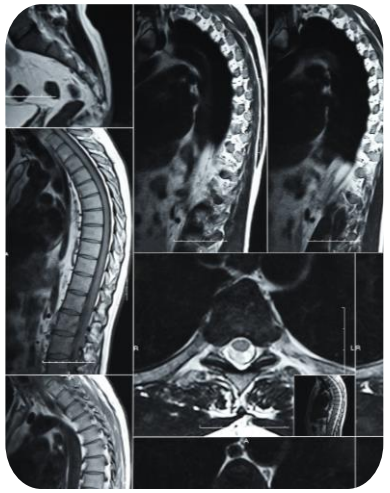
500 000

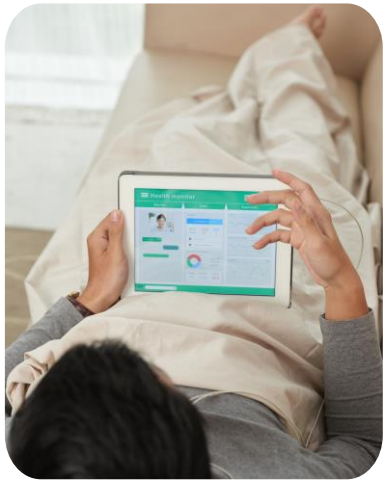
medical devices

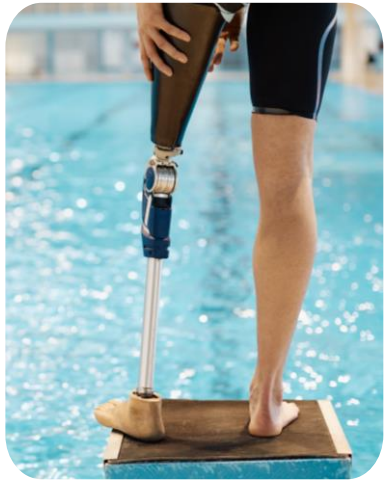
placed on the market within EU with a very broad range of application











Product need to be **safe for the patient** no matter where they are designed or produced

Poll 2

What is driving the classification of medical devices?

Poll 2

A The classification assigned to similar products on the market

B The intended purpose assigned by the legal manufacturer

C The usage within a hospital environment

Answer Poll 2

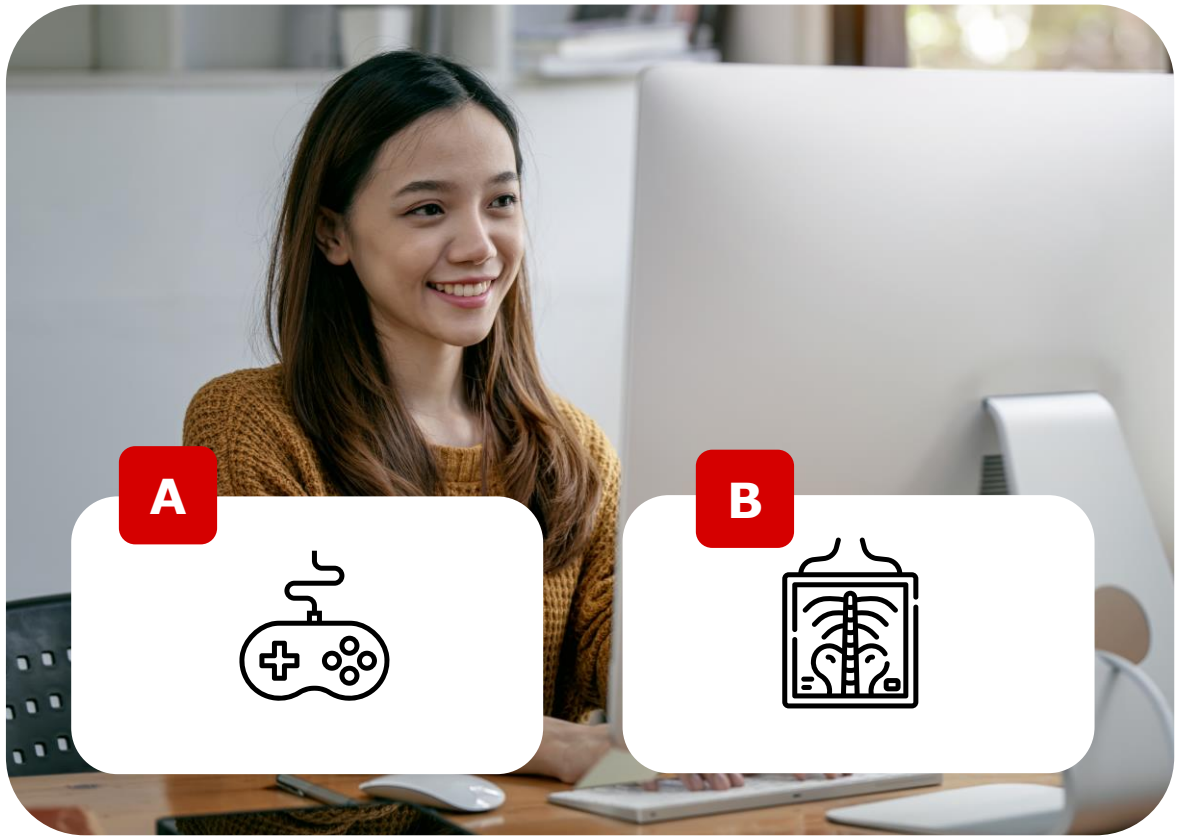
A The classification assigned to similar products on the market

B The intended purpose assigned by the legal manufacturer

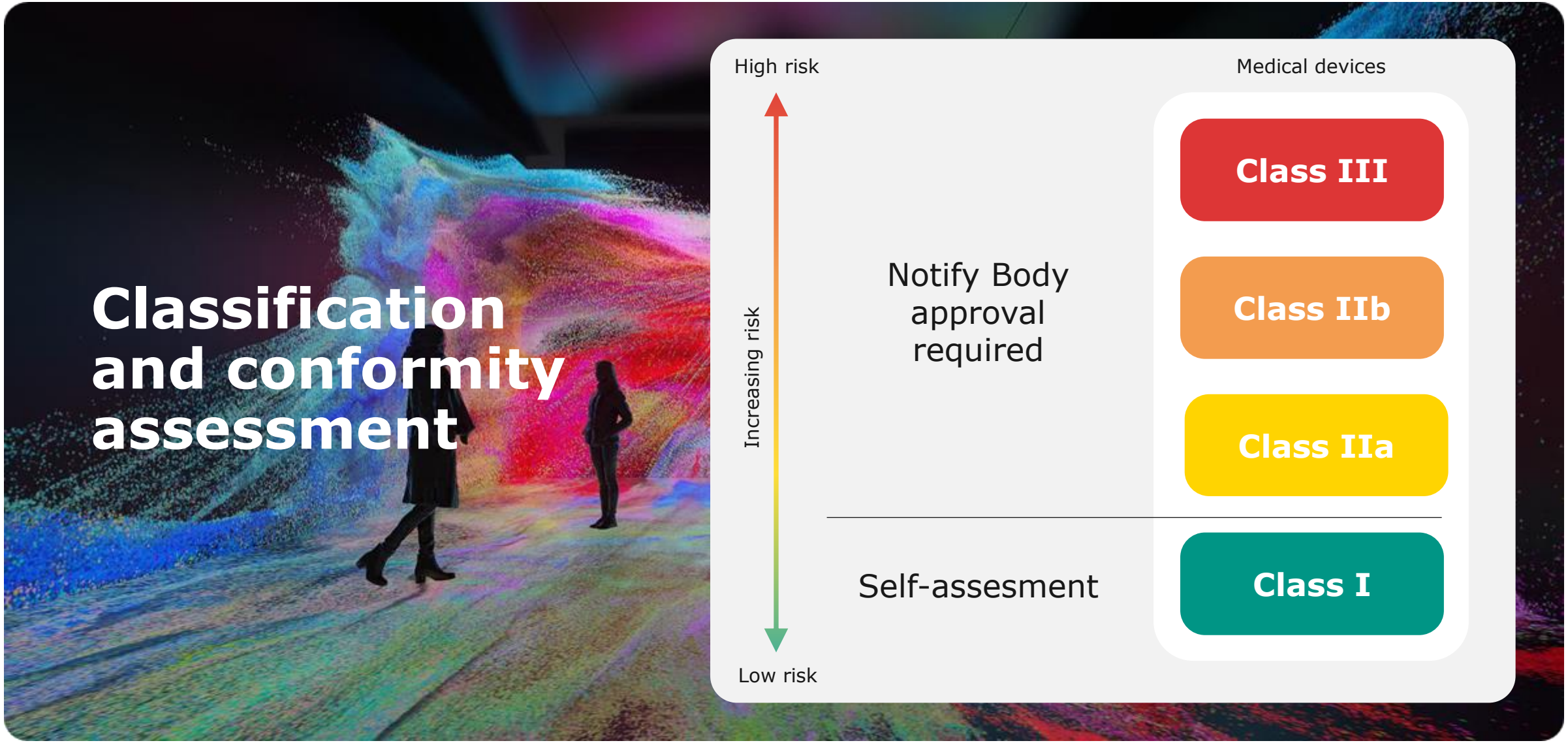
C The usage within a hospital environment

What is a medical device?

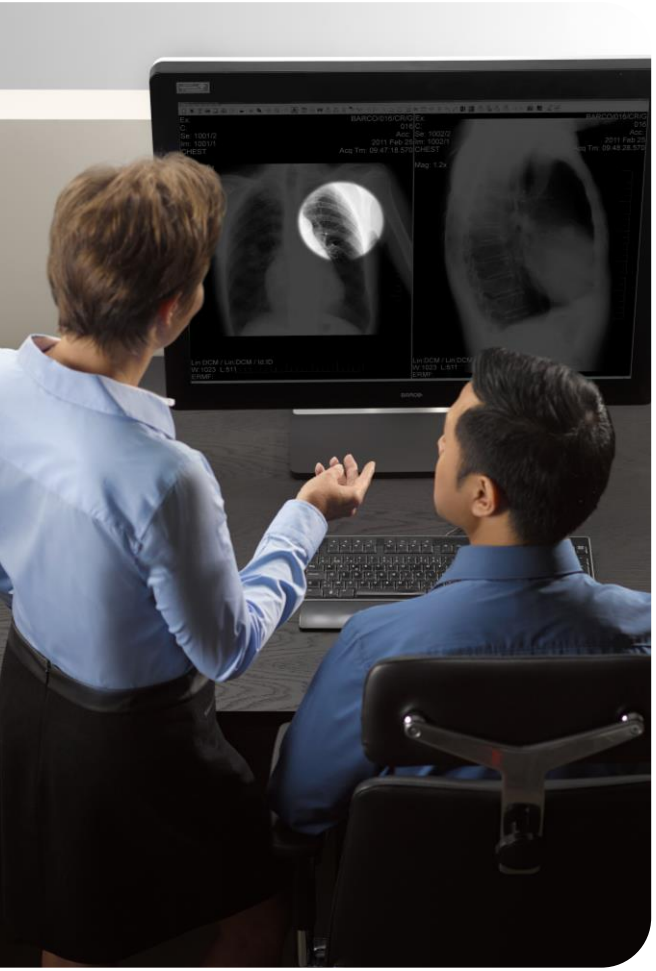
The intended purpose **assigned by the legal manufacturer**



Classification and conformity assessment



How existing displays are affected



What is the intended purpose?

Medical device or not?

YES

Classification based on ALL 22 rules

RULE 10 applies

Class IIa

The significance of rule 10 of the MDR

Class IIa

Class IIa

Rule 10 covers a whole range of equipment in various fields for capture of physiological signals, as well as specifically therapeutic and **diagnostic radiology**.

A diagnostic display is an **active device** and is **intended for diagnosis** because the display **supplies information** for **diagnosing** physiological conditions, states of health, illnesses or congenital deformities.

A diagnostic display is intended to **allow direct diagnosis** because it **provides decisive information for the diagnosis**.

Portfolio

Class IIa

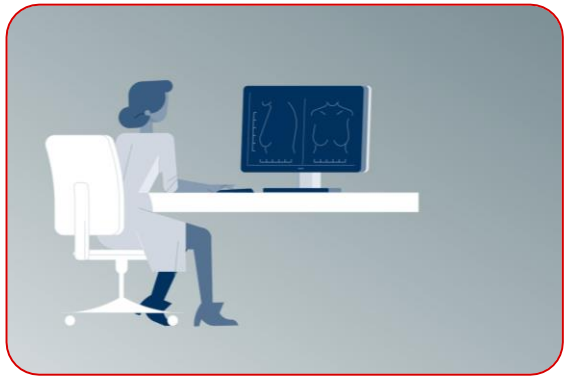
Breast imaging display systems

Radiology display systems

Digital Pathology displays

Dental displays

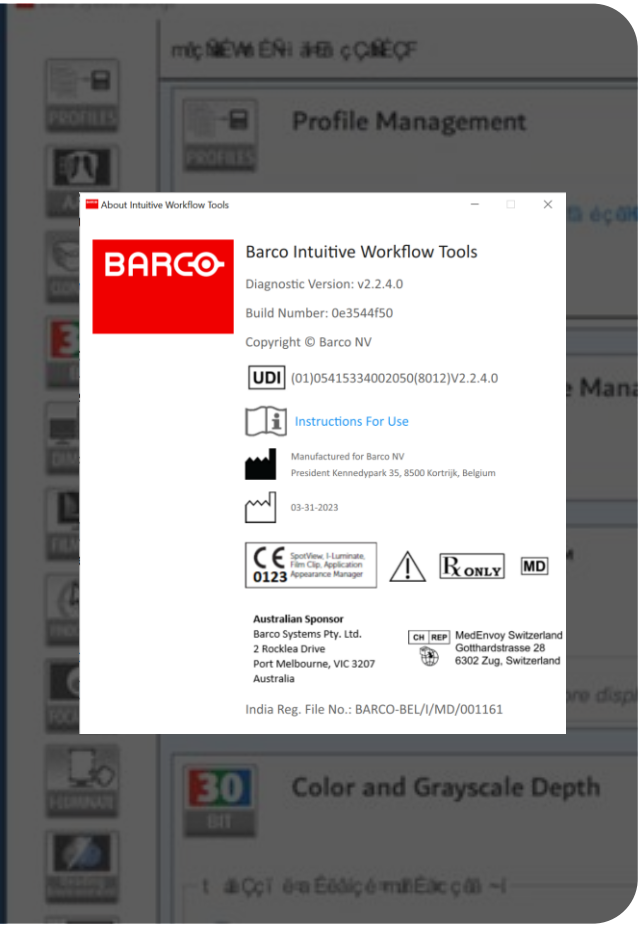
QAWeb Enterprise



Intuitive workflow tools

Spotview,
I-Luminate, AAM,
Filmclip

How does it affect our IWT software solution?



What is the intended purpose?

Medical device or not?

YES

Classification based on ALL 22 rules

RULE 11 applies

Class IIa

Class IIa

How does it affect our QAWeb Enterprise software solution?

What is the intended purpose?

Accessory to a medical device or not?

YES

Driving or influencing?

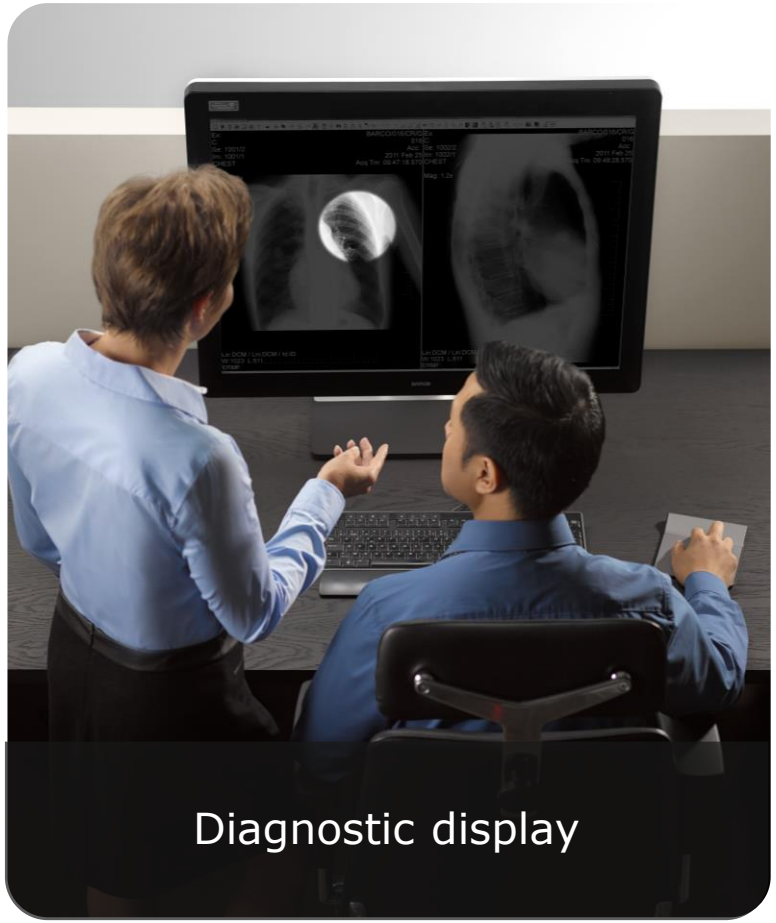
YES

Accessory to medical device

Following class of the devices supported

Barco classification summary

Class IIa



Class I

Displays with similar intended purpose are classified as class I

Other manufacturer use ± **the same intended purpose**

- This product is intended to be used in displaying and viewing digital images for **review, analysis and diagnosis** by trained medical practitioners. It does not support the display of mammography images for diagnosis.
- … is intended to be used in **displaying and viewing medical images for diagnosis** by trained medical practitioners. It is not meant to be used for digital mammography.
- Monitor is intended to be used in **displaying and viewing digital images for diagnosis** of X-ray or MRI, etc. by trained medical practitioners. The device does not support the display of mammography images for diagnosis.

Rule 10 is not considered

Class IIa

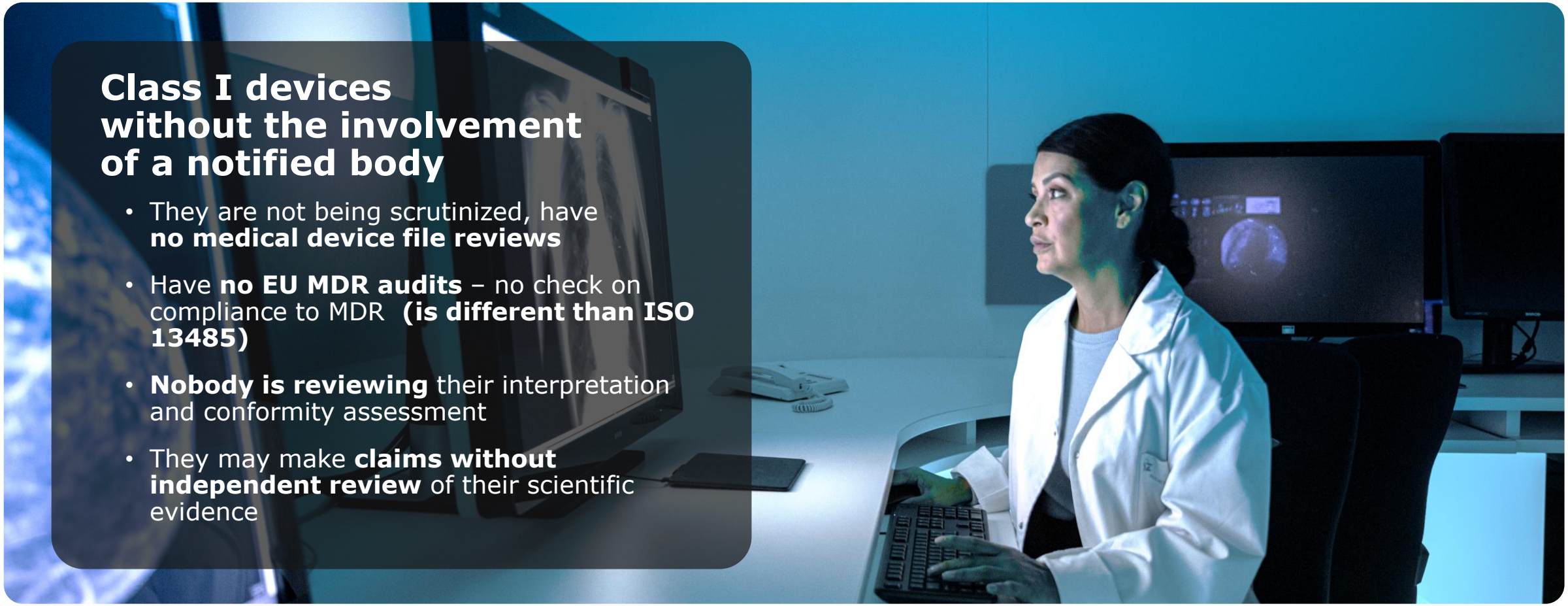
What it takes to receive class IIa certification

Class I devices are placed on the market after **self-certification** by the manufacturer

Class IIa devices are placed on the market after a **notified body assessment** and **certification**

- **Quality Management System is audited** to be in line with EU MDR
- **Technical documentation** assessed by experts on performance and safety
- **Clinical evaluations** assessed by Medical Expert to ensure **scientific validity** on claims and intended purpose
- Yearly audits to ensure our files and systems are **state of the art at all times**

The hidden risks that class I presents in diagnostic environments



Class I devices without the involvement of a notified body

- They are not being scrutinized, have **no medical device file reviews**
- Have **no EU MDR audits** – no check on compliance to MDR **(is different than ISO 13485)**
- **Nobody is reviewing** their interpretation and conformity assessment
- They may make **claims without independent review** of their scientific evidence

How can you recognize a class IIa device?

Label

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 082788 0022 Rev. 00

Manufacturer: Barco NV, President Kennedypark 35, 8500 Kortrijk, BELGIUM

SRN Manufacturer: BE-MF-000000690

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 082788 0022 Rev. 00

Report No.: 713235464

Valid from: 2023-01-27
Valid until: 2028-01-26

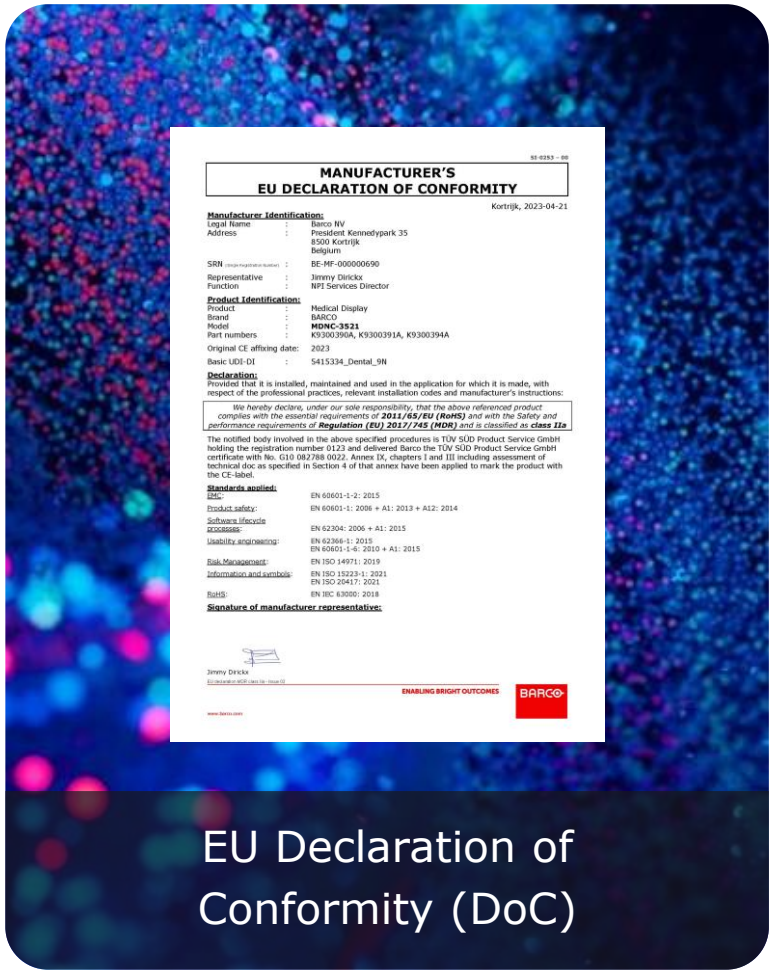
Issue date: 2023-01-27

Christoph Dicks
Head of Certification/Notified Body

Page 1 of 2
TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

ZERTIFIKAT ◆ CERTIFICATE ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Scope MDR certificate



MANUFACTURER'S EU DECLARATION OF CONFORMITY

Kortrijk, 2023-04-21

Manufacturer Identification:
Legal Name : Barco NV
Address : President Kennedypark 35, 8500 Kortrijk, Belgium
SRN : BE-MF-000000690
Representative : Jimmy Dirickx
Function : NPI Services Director

Product Identification:
Product : Medical Display
Brand : BARCO
Model : **MDNC-3521**
Part numbers : K9300390A, K9300391A, K9300394A
Original CE affixing date: 2023
Basic UDI-DI : 5415334_Dental_9N

Declaration:
Provided that it is installed, maintained and used in the application for which it is made, with respect of the professional practices, relevant installation codes and manufacturer's instructions:

*We hereby declare, under our sole responsibility, that the above referenced product complies with the essential requirements of **2011/65/EU (RoHS)** and with the Safety and performance requirements of **Regulation (EU) 2017/745 (MDR)** and is classified as **class IIa***

The notified body involved in the above specified procedures is TÜV SÜD Product Service GmbH holding the registration number 0123 and delivered Barco the TÜV SÜD Product Service GmbH certificate with No. G10 082788 0022. Annex IX, chapters I and III including assessment of technical doc as specified in Section 4 of that annex have been applied to mark the product with the CE-label.

Standards applied:

EMC:	EN 60601-1-2: 2015
Product safety:	EN 60601-1: 2006 + A1: 2013 + A12: 2014
Software lifecycle processes:	EN 62304: 2006 + A1: 2015
Usability engineering:	EN 62366-1: 2015 EN 60601-1-6: 2010 + A1: 2015
Risk Management:	EN ISO 14971: 2019
Information and symbols:	EN ISO 15223-1: 2021 EN ISO 20417: 2021
RoHS:	EN IEC 63000: 2018

Signature of manufacturer representative:

Jimmy Dirickx

ENABLING BRIGHT OUTCOMES

EU Declaration of Conformity (DoC)

Poll 3

Which of the following statements is not correct?

Poll 3

A	B	C	D
Class I medical devices can be self-certified whilst class IIa medical devices need a notified body approval before they are put on the market	Only products designed and/or manufactured in the EU need to comply with the EU MDR	On the product label of a class IIa product, the CE Mark is always combined with notified body identification number	Manufacturers of class IIa devices can only make claims when they have sufficient scientific evidence

Answer Poll 3

A	B	C	D
Class I medical devices can be self-certified whilst class IIa medical devices need body apnotified proval before they are put on the market	Only products designed and/or manufactured in the EU need to comply with the MDR	On the product label of a class IIa product, the CE Mark is always combined with notified body identification number	Manufacturers of class IIa devices can only make claims when they have sufficient scientific evidence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BarcoHealth on LinkedIn & Twitter


Any questions?
MDR
Class IIa
Ensuring
diagnostic
confidence


Visioneering a bright tomorrow