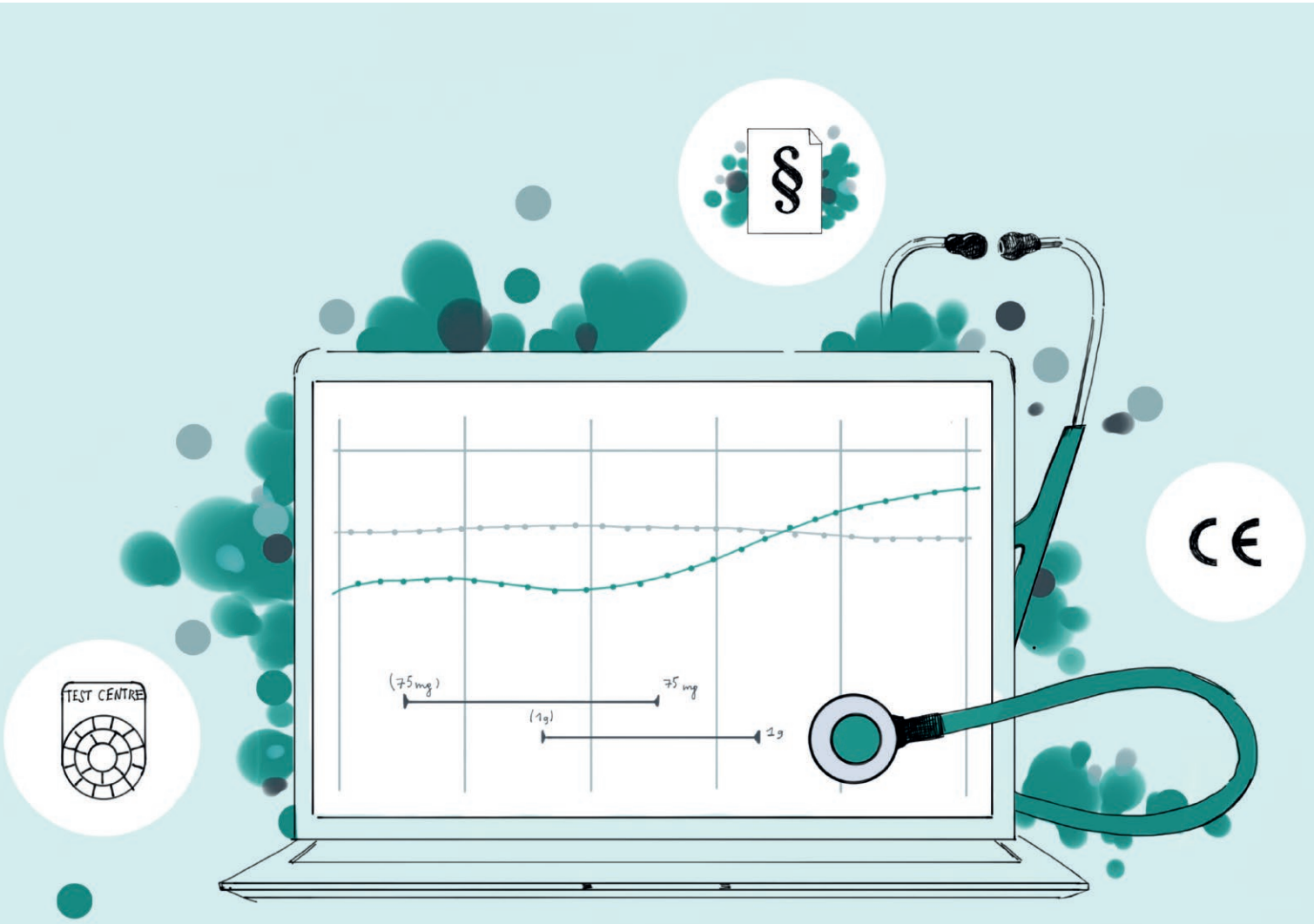
xtention
IT with care.

Software as a medical device



Get your software MDR ready! More stringent requirements, stricter regulations, more obligations for software as a medical device.

More and more frequently, software needs to be defined as a medical device. At the same time, operators need to adhere to more stringent requirements and stricter regulations. We provide you with guidance and support for everything related to software as a medical device so you know exactly what to expect and what you need to consider.

We keep an eye on your software

The complete solution for all social care institutions

We provide you with guidance and support for everything related to software as a medical device so you know exactly what to expect and what you need to consider. Our expertise and comprehensive package of measures are at your disposal, helping you ensure that your medical devices are compatible and can be operated in accordance with legislation.

Get your software MDR ready!

Medical devices will be subject to stricter requirements as the transition period for the new European Medical Device Regulation (MDR) comes to an end. Operators will also face stricter rules and have more obligations, especially for software as a medical device.

Software as a medical device

As an institution that uses or adapts software, you could be affected by the MDR (EU Medical Device Regulation). We are happy to advise you and will explain the differences.

Software adaptation

Adherence to legal requirements for individual software enhancements (produced in house)

Example: hospital-specific add-on for HIS

Measures:

- Analyse existing enhancements
- Classify as medical device yes/no
- Define intended purpose
- Set up QM system
- etc.

Software operations

Ensure compatible operation of medical devices

Example: Check manufacturer's information before updates

Measures:

- Medical software compliance check
- Add it to the inventory list or device file
- Follow processes for compatible operations
- Manage risk in accordance with 80001
- etc.

What you need to consider:

- Which software is approved as a medical device in your institution?
- Is compatible operation guaranteed in accordance with the manufacturer's specifications?
- Is the software listed in an inventory?
- Do you perform regular safety checks on your software?
- Do you adapt your software as a medical device or do you develop enhancements yourself based on your medical device software?
- Do your in-house developments count as medical devices?

Medical software compliance check

Medical software compliance check

Check your entire software landscape with regard to medical device compliance

x-tention's medical software compliance check allows you to identify and analyse software medical devices quickly and easily. Our tool features a comprehensive set of measures that ensures complete transparency for compliance with all regulatory requirements.

How it works

Know what you're using!

1. Analysis – Kick-off workshop

- Become familiar with the regulatory framework
- Use templates to collect information about your software landscape

Result: Complete list of software

Know what counts as a medical device!

2. Research – medical device, yes or no?

- Classify software devices according to manufacturer's specifications
- Present the medical device analysis table

Result: Medical device analysis table

Know what counts as compliant!

3. Compliance check – workshop

- Joint compliance check based on various examples

Result: Compliance certificate or action plan

Recommended measures for legally compliant operations:

- Where incompatibilities exist, transition to legally compliant operations
- Implement an electronic inventory or device file and map the whole software landscape
- Perform medical software compliance checks before updates and version changes
- Implement a recurring medical software compliance check to guarantee ongoing compatibility
- Set up a risk management system in accordance with IEC 80001

Recurring safety checks

Guarantee operability and patient safety

We have been working with TÜV Austria since 2019, meaning you will have access to an accredited partner that will perform periodic technical safety checks (wSTP/STK) on your software as a medical device. Just as with physical medical devices, software as a medical device is required by law to be checked regularly. Take the first step toward ensuring the safety of your software as a medical device with regular checks.

In cooperation with

TÜV AUSTRIA

PRÜFBLATT

wSTP-W/19/0004-205050

Wiederkehrende sicherheitstechnische Prüfung von Medizinprodukten

Testmandant Wien			
Objektbezeichnung:	Software als MP	Fabr.-Nr.:	1545_1401896
Hersteller:	GE Healthcare	Prüfzyklus:	12 Monate
Type:	Centricity High Acuity Anaesthesia	SW-Version:	1902.0713
Techn. Daten:	CE		
Abteilung:	Zentral OP	EDV-Nr.:	SW_00047182
Raum:	OP5	Inv.-Nr.:	-
Kostenstelle:	82000014795		

Beurteilung

a) Es wurden keine Mängel festgestellt.

Behobene Mängel:

- DLL's sind nicht aktuell

Prüfdatum: 11.09.2019

Mess- und Prüfmittel: L4 — TÜV AUSTRIA SERVICES GMBH

Prüfergebnisse

Geprüft nach QS-Checkliste: FPR000
und Hersteller-Checkliste: sw_centric(Rev. 0)
(nur zutreffende Prüfpunkte angeführt)

1.	Testpatient	Ist: Muster	OK
2.	Start	Ist: 08:27	OK
3.	Ende	Ist: 14:32	OK
4.	Aufruf aus Startmenü		OK
5.	Login		OK
	Intraoperativ		
6.	Anwesenheit MT (namentlich)		OK
7.	CDI Version	Ist: 550	OK
8.	MAC/IP Digibox		OK
9.	Anzahl der Ports	Ist: 2	OK
10.	Einzubindende Geräte		OK
11.	verwendete Kabel		OK
12.	Prüfen der Treiber (DLL)		OK

Image: Example test report

Consulting

Consulting for your in-house development

MDR: Have you considered your in-house developments?

- Which additional programs do we develop ourselves based on medical devices?
- When do we count as a manufacturer ourselves?

With the following set of services, we're the partner you can rely on:

Classification of customer-specific developments in accordance with the MDR

Analysis — **Classify medical devices** — **Create actions**

Know what you're using!

1. Pre-analysis – workshop

- Workshop to identify in-house developments and list them systematically, including documenting how they work

Result: In-house overview

Know what counts as a medical device!

2. Classified as a medical device – yes or no?

- Assess which in-house developments count as medical devices and are subject to the MDR, and formulate an intended purpose for them

Result: In-house medical devices Table

Know what the MDR requires you to do!

3. Create actions

- Create an action plan for fulfilling MDR Article 5 Paragraph 5

Result: Action plan in-house products

Guidance for ISO 13485

We help you set up a quality management system for medical devices in accordance with ISO 13485. You will benefit from our many years of experience in the healthcare sector, and our practical template packages will save you valuable time.

QMS complete template package — **Fill in templates** — **Introduce QMS**

Benefits

- **We are experts**
  We know the sector and understand the daily challenges you face in the health and social care system.
- **Compact and transparent overview**
  Adding software to your inventory as a medical device and performing regular safety checks will ensure that you are prepared for external inspections.
- **Implement measures easily**
  We help you take your in-house developments all the way to MDR compliance.
- **Full control with little effort**
  Our employees continually undergo training and certification to continue building their expertise.

x-tention group

How to get in touch

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