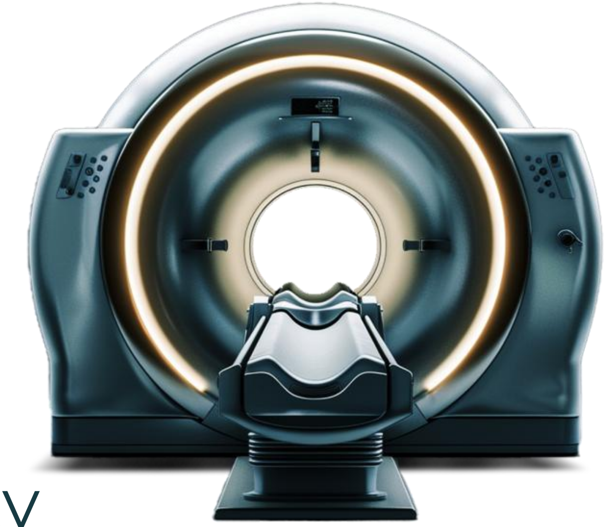
# A Checklist for EU RED (EN 18031) Compliance

1. Map your device connectivity (Wi-Fi, BLE, cellular)
2. Review product scope under RED vs MDR
3. Apply EN 18031-series standards
4. Create a security-by-design process
5. Build technical documentation for CE conformity
6. Set up a vulnerability handling process and disclosure policy



# 1. Map Your Device Connectivity

**Why it matters:**
RED applies specifically to radio equipment, meaning any device with a wireless interface (Wi-Fi, Bluetooth, cellular, etc.).

- ❑ Document every radio interface used in the device.
- ❑ Include hidden or low-energy components (e.g., BLE beacons).
- ❑ Map communication paths between modules and external systems.

# 2. Review Product Scope Under RED and MDR

## Why it matters:

Medical devices are typically regulated under the Medical Device Regulation (MDR), but if they include wireless communication, RED may also apply.

❑ Identify whether your device is strictly medical (under MDR) or also falls under RED due to connectivity.

❑ Devices not classified as “medical”, such as remote patient monitors, are likely fully RED-regulated.

❑ Understand overlapping obligations if both apply.

# 3. Apply EN 18031-series Standards

## Why it matters:

The EN 18031-series Standards will become mandatory in August 2025.

- ❑ Start implementing cybersecurity measures aligned for:
  - ❑ EN 18031-1: General principles
  - ❑ EN 18031-2: Risk assessment and threat analysis
  - ❑ EN 18031-3: Security requirements by class of device
- ❑ Conduct structured threat modeling and risk classification based on these guidelines.

# 4. Create a Security-by-Design Process

## Why it matters:

RED mandates proactive security - not just afterthought patching.

- □ Embed security into product development, from premarket to postmarket.
- □ Use secure coding and static code analysis.
- □ Define and implement access controls, secure boot, encryption, and update validation mechanisms.
- □ Train engineering teams on secure SDLC practices.

# 5. Build Technical Documentation for CE Conformity

**Why it matters:**

To apply the CE mark under RED, manufacturers must provide a Declaration of Conformity (DoC) and supporting technical files.

- ❑ Document your threat modeling, risk analysis, and implemented controls.
- ❑ Provide results from testing (e.g., penetration testing, vulnerability scans).
- ❑ Include your EN 18031 compliance mapping.
- ❑ Maintain this documentation for inspection by Notified Bodies or market surveillance.

# 6. Set Up Vulnerability Handling Process and Disclosure Policy

## Why it matters:

RED requires postmarket protection of devices, not just secure design (premarket).

- ❑ Establish a coordinated vulnerability disclosure policy.
- ❑ Monitor for new CVEs and zero-days affecting your components.
- ❑ Monitor, prioritize, and mitigate vulnerabilities in a timely and traceable manner.
- ❑ Inform customers and regulators if critical vulnerabilities are found.

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**John Chenoweth**
Chief Product Security Officer
Elekta

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