TÜVNORD

YOUR PATH TO CERTIFICATION

MDR Certification Readiness Checklist

Points 1 to 3: Essential actions your organization must take before pursuing MDR certification

1 Regulatory Readiness

- ☐ Confirm that the device is qualified as a medical device, classified according to Annex VIII, and a suitable conformity assessment procedure is chosen.
- ☐ Non-EU manufacturers must appoint an Authorized Representative within the EU to act as their legal and communication representative.
- ☐ Select a Notified Body with the appropriate qualification for your products.

2 Technical & Clinical Documentation

- ☐ Establish, document and maintain an MDR Compliant Quality Management System
- ☐ Verify that the technical documentation for all products within the certification scope complies with Annex II and III.
- ☐ Have your clinical documentation aligned with the new requirements of the MDR Annex XIV and XV.

3 Post-Market & Surveillance Compliance

- ☐ Establish processes for incident reporting, corrective actions, and periodic safety updates.
- ☐ Prepare the procedure informing the NB about significant changes.

4 MDR certification procedure TÜV NORD

Inquiry & offer preparation ▶ Order for the conformity assessment procedures, followed by TÜV NORD application review ▶ Setting up the adequate audit program including TD assessment and audits relevant for certification ▶ Assessment of the technical and clinical documentation ▶ QM system audit Stage 1 and 2 ▶ TD and QM nonconformity management ▶ Release and certification decision by TÜV NORD ▶ **Issue of certificate and release into EUDAMED database**

You have all the documents and would now like to request a proposal?

CONTACT US HERE

Do you still have questions about certification?
Write to us: medical@tuev-nord.de