OUR PATH TOWARDS COMPLIANCE

New EU MDR Regulations

Why has the EU introduced the new MDR?

To ensure consistently high level of health and safety protections

To facilitate free and fair trade throughout the EU for the medical device industry

To adapt to the significant technological and scientific progress of the past 20 years

Introduction

In May 2017, the European Commission introduced new regulations for medical devices (MDR). All medical device manufacturers and distributors – including Arjo – are required to abide by the new regulations by **May 2021** with a grace period until the expiry of the current CE certificate. For Arjo´s Class II and Class III products this is valid until **June 2023**.

Some of the key requirements include:

- Stronger requirements for Post Market Surveillance planning and implementation, vigilance reporting and handling of field safety corrective actions
- Changes to the classification of medical devices
- Reinforcement of rules on clinical evaluation reports (CER) and product technical documentation

How will we get there?

I. EARLY PLANNING

In 2017, Arjo had already kicked off our Management System Plan and appointed a project team.

II. EDUCATION & ALIGNMENT

In January 2018, Arjo organised a global training conference for over 40 participants, including 2 days of training and a gap assessment workshop.

III. GLOBAL PROJECT

A global Project Manager has been appointed to drive resource allocation, steering committee meetings, and actions defined per the project plan.

IV. EXECUTION

In January 2021, Arjo obtained MDR certification for intermittent compression systems and associated pumps in class IIa as well as the following class Im devices: medical beds, patient lifts, and bathing systems with measuring functions. All remaining Class I devices are expected to be MDR compliant by May 26, 2021. All remaining devices class IIa and above are on track to full certification before June 2023.

Arjo EU MDR implementation – Summary

As customer safety and satisfaction has always been our priority, Arjo remains fully committed to complying with all international regulations, including the new Medical Devices Regulation (MDR) 2017/745.

Our focus is to ensure continued availability of high quality products that comply with all relevant regulations, including ensuring that our products retain their necessary CE markings and CE certifications.

More information on our commitment to quality and regulatory compliance can be found on **arjo.com/compliance**.

- In 2018, we launched an extensive, cross-functional program to ensure we will meet the new requirements effectively.
- **Class I medical devices:** In January 2021 we received MDR certification for medical beds, patient lifting devices and bathing systems with measuring functions. All remaining class I devices are on track to become MDR compliant by May 2021.
- **Class IIa and III medical devices:** Our current CE certification allows Arjo to CE mark our medical devices until June 2023. Intermittent compression systems and associated pumps have been fully MDR certified in January 2021. All other product groups are on track to achieve similar certification by or before June 2023.

Arjo.A00041.3.0.INT.EN • APRIL 2021

www.arjo.com