EU MDR Distributor Compliance Manual for MDR

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This Manual is intended for Tricefy distributors located in the EU region. The purpose of this Manual is to provide instruction and guidance for complying with the EU Medical Device Regulation (MDR, EU 2017/745), which goes into application on May 25, 2021.

The EU MDR has introduced a new term, Economic Operator, which is defined as a manufacturer, an authorized representative, an importer, a distributor, or the person referred to in Article 22(1) and 22(3). The Manual addresses the responsibility of EU distributors regarding

- Labeling
- Translations
- Post Market Surveillance Instructions
  -Complaints
  -Feedback
  -Field Safety Correction
- Product Review

EU distributors, please ensure that you are compliant with the contents of this Manual, found here:

EU Distributor User Manual for MDR.pdf