MD Law.eu

Information Platform on EU Medical Devices Regulation

IVDR IMPLEMENTATION TOOL

MAY 2020

In-vitro Diagnostic Medical Devices Regulation **Technical Documentation Structure**

POWERED BY OBELIS GROUP

Obelis
CREATES COMPLIANCE FOR SAFER MARKETS

Medical Devices
Technical Documentation Guidance

Introduction

The requirements for technical documentation are laid down in...

The details included in the documentation will depend on...

Where harmonised standards have been applied...

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Generalities

When building the Technical Documentation of an In Vitro Diagnostic Medical Deice, there are few points which should be taken into consideration

- ...

Language of the technical documentation

The Competent Authority may request presentation of...

Intervention of Notified Bodies in technical documentation review:

The Technical Documentation of the following devices will be reviewed by the notified body as part of the conformity assessment procedure:

- Class D devices...

- For Class D devices for which...
  - At least one representative device...

Steps to follow when planning the Technical Documentation:

- Familiarize yourself with the IVD Regulation and all published guidances.
- Ensure ...

Technical Documentation Content

Please find below details on the index and content of a Technical documentation:

1. Device description and specification, including variants and...	
Device description and specifications	✔ The device description should enable understanding of the design, composition and... ✔ ... ✔ Describe the parts...
2. Information to be supplied by the manufacturer	