List of Regulatory Requirements

1. General Information

This document lists the applicable standards, norms and regulations for the medical device.

It is regularly updated pursuant to the SOP Update of Regulations and implications of changed requirements are assessed.

Regulatory references:

- ISO 13485:2016 Sections 5.6.2 and 7.3.3

  Use this template to give yourself an idea of the necessary structure and contents. Ideally, this documentation is maintained best in a spreadsheet / excel file format.

2. Regulations

Regulation	Applicability	Description	Jurisdiction	Review Cycle	Last Review	Notes	Links
(GDPR) General Data Protection Regulation (...)	Applies	Regulates the protection of natural persons with regard to the processing of personal data and on the free movement of such data.	EU	Annual			EU law

3. National Laws

Regulation	Applicability	Description	Jurisdiction	Review Cycle	Last Review	Notes	Links
(MPDG) German Medical Devices Law (...)	Applies	Replaces D old MPG		Annual	-		German law

4. Standards and Norms

Regulation	Applicability	Description	Jurisdiction	Notes	Review Cycle	Last Review	Links
EN ISO 13485:2016 + AC:2018 + A11:2021 (. . .)	Applies	QM Systems	International		Annual	-	ISO

5. Guidances

Regulation	Applicability	Description	Jurisdiction	Notes	Review Cycle	Last Review	Links
MDCG 2018-1 rev4 04-2021 (. . .)	Applies	Guidance on basic UDI-DI and changes to UDI-DI	EU		Annual	-	EU text