# 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 | Notes | Review Cycle | Last Review | 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](https://eur-lex.europa.eu/eli/reg/2016/679/oj) |
| (…) |  |  |  |  |  |  |  |

## 3. National Laws

| Regulation | Applicability | Description | Jurisdiction | Notes | Review Cycle | Last Review | Links |
| --- | --- | --- | --- | --- | --- | --- | --- |
| (MPDG) German Medical Devices Law | Applies | Replaces old MPG | D |  | Annual | - | [German law](https://www.gesetze-im-internet.de/mpdg/) |
| (…) |  |  |  |  |  |  |  |

## 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](https://www.iso.org/standard/59752.html) |
| (…) |  |  |  |  |  |  |  |

## 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](https://health.ec.europa.eu/system/files/2021-04/md_mdcg_2018-1_guidance_udi-di_en_0.pdf) |
| (…) |  |  |  |  |  |  |  |

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