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**Document title**

Instruction for use for the author of this document: blue text is background information and is intended to assist during preparation of this document. This background information must be deleted or replaced before the document is released. The final version may only contain product specific contents. Wherever possible, references should be used. (Redundant information shall be avoided).

Device: Device

Basic UDI-DI: Basic UDI-DI

Manufacturer: Manufacturer name

Manufacturer SRN: Manufacturer SRN

Table 1 Signatures

|  |  |  |  |
| --- | --- | --- | --- |
|  | Name and function | Signature | Date |
| Author |  |  |  |
| Review |  |  |  |
| Release |  |  |  |

Table 2 Document history

|  |  |  |  |
| --- | --- | --- | --- |
| Version | Date | Name and function | Change |
|  |  |  |  |

# Directives and Regulations

Table 3 Directives and Regulations.

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Name | Concerning sections | Rationale |
| Directive 93/42/EEC (as last amended) | COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 (as amended) concerning medical devices | All sections  Only partially |  |
| MDR | Regulation (EU) 2017/745 of the European Parliament and the Council | All sections  Only partially  Section(s) applied: … |  |
|  |  |  |  |

# Harmonized and Technical Standards

This section should contain all standards recognized in every country where the product is intended to be launched.

Table 4 Harmonized and technical standards.

|  |  |  |  |
| --- | --- | --- | --- |
| Reference | Designation | Concerning sections | Rationale |
| ISO 14971:2019 | Medical devices — Application of risk management to medical devices | All sections Only partially |  |
|  |  |  |  |
|  |  |  |  |

# Reference documents or additional information

See GSPR Checklist.

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