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**Appendix 1 – Clinical Evaluation Plan**

|  |  |  |
| --- | --- | --- |
| Device name |  | |
| Basic UDI |  | |
| Date of Clinical Evaluation Plan |  | |
| Clinical evaluator |  | |
| Responsibilities of the members of the team | … | … |
| … | … |
| … | … |
| … | … |
| … |  | |
| … |  | |

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# Reference documents

* ISO 13485 standard, clause 7.3.7
* MDR 2017/745, article 61 and Annex XIV – Part A
* MEDDEV 2.7.1 rev 4
* MDCG 2020-6 Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC (04/2020)
* MDCG 2020-5 Clinical Evaluation – Equivalence A guide for manufacturers and notified bodies, April 2020

# Scope of the clinical evaluation

## Identification of device(s)

|  |  |
| --- | --- |
| **Product details** | |
| Name of medical device or family of medical devices |  |
| … |  |
| … |  |
| … |  |
| Classification according to Annex VIII of 2017/745/EC and product identification | |
|  | |

## Device description

|  |
| --- |
| Description of device in alignment with technical documentation |
|  |
| Technology used |
|  |
| … |
|  |

## Intended purpose

|  |
| --- |
| Intended purpose in alignment with Instructions for Use (IFU) with clear indications |
|  |
| … |
|  |
| … |
|  |
| … |
|  |
| … |
|  |
| … |
|  |
| … |
|  |
| Alternative technology |
|  |

…

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