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**Appendix 2 – Clinical Evaluation Report**

|  |  |  |
| --- | --- | --- |
| Device name |  | |
| Basic UDI Applicable |  | |
| Date of Clinical Evaluation Plan |  | |
| Responsibilities | … |  |
| … |  |
| … |  |
| … |  |
| … |  |
| Start date of the clinical evaluation |  | |
| Expected date to finish the clinical evaluation |  | |

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# Executive summary

|  |
| --- |
| Executive summary |
|  |

# 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 |
|  |
| … |
|  |
| … |
|  |

## …

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