1. General Information

This document describes the latest device details and as well as details for previous device versions.

Regulatory references:

- MDR Annex II Para. 1.2

  Use this template to give you an idea of the necessary structure and contents. Ideally, this documentation is maintained best in a spreadsheet / excel file format. Think of every heading as a separate sheet / tab.

2. Current Medical Device Version

Fill out the table below for every installed device version. For example (in B2B business), use one row to describe every customer site the software device is installed at.

Device Name	Product Status	Release Date	Purpose	Device Identifier (DI)	Product Identifier (PI)	Customer Details	Customer Point of Contact	App Store URL	Commentary
<enter device name>	<released / in trial / etc.>	(...)	<e.g. clinical use>	(...)	(...)	(...)	(...)	(...)	(...)

3. Previous Versions

Use the table below to document your device's versions history.

Device Name	Device Version	Release Date	Decommissioning Date	Device Identifier (DI)	Product Identifier (PI)	Commentary
<enter device name>	V.1.1	(...)	(...)	(...)	(...)	(...)
<enter device name>	V.1.0	(...)	(...)	(...)	(...)	(...)

4. Similar Devices

Product Name	Manufacturer	Country of Origin	Additional Information	Device Identifier (DI)
<enter device name>	(. . .)	(. . .)	(. . .)	(. . .)
