# 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> | (…) | (…) | (…) | (…) |

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