**[Insert Device name]**

**Device Master Record**

**Prepared By**

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| --- | --- |
| [Name] | [Role/ Function] |
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**Approved By**

|  |  |
| --- | --- |
| [Name] | [Role/ Function] |

**Revision**

[V.#]

**Date**

[dd-MON-yyyy]

**DMR Type:**  Pre-Market DMR (Clinical Study)

DMR (Commercial Distribution)

**Product Description:**

**Catalogue Number(s):**

Add if applicable

| **Catalog No.** | **Description** |
| --- | --- |
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|  |  |

**Product Summary:**

1. **Device Specifications:**

Final Assembly / Components / In-Process Specifications:

| **Specification** | **Title** |
| --- | --- |
|  |  |
|  |  |

1. **Production Process Specifications:**

Operating Procedures, Work Instructions, and Forms:

| **Document No.** | **Title** |
| --- | --- |
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1. **Quality Assurance Procedures and Specifications:**

Quality Assurance Procedures, Work Instructions and Forms including documents for receiving inspection:

| **Document No.** | **Title** |
| --- | --- |
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1. **Packaging and Labelling Specifications:**
   1. **Packaging Specifications:**

| **Specification** | **Title** |
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* 1. **Labelling Specifications:**

| **Specification** | **Title** |
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* 1. **Packaging and Labelling Procedures, Work Instructions and Forms:**

| **Document No.** | **Title** |
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1. **Installation, Maintenance, and Servicing Procedures and Methods:**

[No product within the scope of this Device Master Record requires installation, maintenance, and servicing at the point of use].

or:

| **Document** | **Title** |
| --- | --- |
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# Document Change Control

The following is the document control for revisions to this document.

|  |  |  |  |
| --- | --- | --- | --- |
| **Version**  **Number** | **Date of**  **Issue** | **Author(s)** | **Brief Description of Change** |
| [[###]] | [[###]] | [[###]] | [[###-###]] |