|  |  |  |
| --- | --- | --- |
| **DMR #:** | | ***<Enter DMR #>*** |
| **DEVICE IDENTIFICATION** | | |
| Device Name: | *<Enter the name of the device>* | |
| Model/Type/Config.: | *<Enter the model, type or configuration of the device, if applicable>* | |

**DEVICE MASTER RECORD INDEX**

*<Not all types of documents specified in this section are relevant for each type or model of device. For a particular device, GT Medical should define which specific documents are to be included. Edit this list carefully to delete any items that are not applicable, and to add any documents that are relevant but are not included. Make sure to use the actual document names and designations as applicable for your type of products and processes.>*

|  | | **Doc #** | **Location** |
| --- | --- | --- | --- |
| **Device Specifications** | | | |
| 1.1 | *<Enter the name of the document. For example: Bill of Materials>* | *<Enter doc #. For example, BOM-0001>* | *<Enter the place where the document can be located. For example, in production area, in binder ABC, in Quality Manual, in inspection or receiving area, etc.>* |
| 1.2 | *<Add others as required>* |  |  |
| 1.3 | *Finished Product Specification* |  |  |
|  |  |  |  |
|  | | | |
| **Production Process Specifications** | | | |
| 2.1 | *<Enter the name of the document.  For example: Manufacturing Procedure>* |  |  |
| 2.2 | *<Add others as required>* |  |  |
| 2.3 | *Production Methods and Procedures* |  |  |
| 2.4 | *Production Environmental Procedures* |  |  |
|  |  |  |  |
|  | | | |
| **Quality assurance procedures and specifications** | | | |
| 3.1 | *<Enter the name of the document.  For example: Final Inspection Procedure>* |  |  |
| 3.2 | *<Add others as required>* |  |  |
| 3.3 | *In Process Items Specification* |  |  |
| 3.4 | *Component Specification* |  |  |
|  | | | |
| **Packaging and labeling specifications** | | | |
| 4.1 | *<Enter the name of the document>* |  |  |
| 4.2 | *Packaging Specifications* |  |  |
| 4.3 | *Labeling Specifications* |  |  |
|  |  |  |  |
|  | | | |
| **Installation, maintenance and servicing procedures and methods** | | | |
| 5.1 | *<Enter the name of the document>* |  |  |
| 5.2 | *<Add others as required>* |  |  |
| 5.3 | *Preventive Maintenance Procedures* |  |  |
| 5.4 | *Calibration Procedures* |  |  |
|  |  |  |  |
|  | | | |
| **Additional Documentation** | | | |
| 6.1 | *<Enter the name of the document>* |  |  |
| 6.2 | *<Add others as required>* |  |  |

**RECORD HISTORY**

|  |  |  |
| --- | --- | --- |
| **APPROVALS** | | |
| Title | Name (Printed) | Signature & Date |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **REVISION HISTORY** | | | | |
| Rev. # | Released Date  (YYYY-MM-DD) | DR # / ECO #[[1]](#footnote-1) | Description of Change | Author |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Design Review (DR) # is to be used during the design process until transfer to production. Engineering Change Order (ECO) # is to be used after design is transferred to production. [↑](#footnote-ref-1)