**Checklist for Quality Manual (In accordance to ISO 13485)**

1. **Purpose and Scope:**

This checklist describes the quality manual established by ……………… (كتابة اسم المنشأة) ……

|  |  |
| --- | --- |
| Activity of the establishment  (نشاط المنشأة) | 🞏 Importation / Distribution 🞏 Authorized Representative  🞏 Other …………………… |
| Excluded from the scope of the quality management system (QMS), and provide justification | (توضيح ما هو خارج نطاق نظام إدارة الجودة مع توضيح المبرر) |

1. **Documented Procedures**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ISO 13485: 2016 (Clause / Sub-Clause)** | **Documented Procedures**  (الإجراءات الموثقة) | **Clause Applicable?**  (هل ينطبق البند) | | | Interaction between the processes of the quality management system  (وصف التفاعل بين عمليات نظام إدارة الجودة) |
| **Yes** | **Not Applicable (N.A)** | **Justification (In case of selecting N.A)** |
| **4.1.6** | Procedures for the validation of the software applications used in the quality management system |  |  |  |  |
| **4.2.4** | Procedure for document control |  |  |  |  |
| **4.2.5** | Procedure for record control |  |  |  |  |
| **5.6.1** | Procedure for management review |  |  |  |  |
| **6.2** | Procedure for establishing and recording competence, training and awareness |  |  |  |  |
| **6.4.1** | Procedure to monitor and control the work environment |  |  |  |  |
| **7.4. I** | Procedure for purchasing |  |  |  |  |
| **7.5.4** | Procedure for servicing activities of medical devices |  |  |  |  |
| **7.5.8** | Procedure for product identification |  |  |  |  |
| **7.5.9.1** | Procedure for traceability |  |  |  |  |
| **7.5.11** | Procedure for preserving the conformity of product |  |  |  |  |
| **7.6** | Procedure for monitoring and measuring equipment. |  |  |  |  |
| **8.2.1** | Procedure for customer feedback gathering |  |  |  |  |
| **8.2.2** | Procedure for complaint handling |  |  |  |  |
| **8.2.3** | Reporting to the SFDA National Center for Medical Devices Reporting (NCMDR) |  |  |  |  |
| **8.2.4** | Procedure for internal audit |  |  |  |  |
| **8.3.1** | Procedure for control of nonconforming product |  |  |  |  |
| **8.3.3** | Procedure for issuing safety alerts |  |  |  |  |
| **8.4** | Procedure for analysis of data |  |  |  |  |
| **8.5.2** | Procedure for corrective actions |  |  |  |  |
| **8.5.3** | Procedure for preventive actions |  |  |  |  |

1. **Attestation**

* **We pledge that all data provided in this checklist are correct.**
* **We undertake to provide Quality Manual which comply with the Saudi Standard SFDA.MD/GSO ISO 13485) or its equivalent /Clause (4.2.2) during the inspection visit.**

**Name: …………………………….**

**Signature: …………………………**

**Job Title: …………………………..**

**Date: ………………………………**