Auditing Organization:

AOID:

AO Assessment:  Initial Surveillance Re-recognition  Special

Witnessed Audit Reference: WA#

|  |  |  |
| --- | --- | --- |
|  | **Manufacturer** | **Audited facility  (if different from the Legal Manufacturer)** |
| **Name** |  |  |
| **Physical address** |  |  |
| **Contact person name** |  |  |
| **Contact person function** |  |  |
| **Email** |  |  |
| **Phone** |  |  |

|  |  |  |
| --- | --- | --- |
| Contract, audit and certificate | | |
| Reference of AO-Manufacturer contract |  | |
| Scope of certification |  | |
| Audit type | **Initial**  **Surveillance: 1 2**  **Recertification** | **Audit of supplier**  **Unannounced**  **Other special audit** |
| Scope of audit |  | |
| Certificate reference |  | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Activities performed at the audited facility** | | | | | | | | |
| Management  Human resources  Design  Engineering | Inspection/Quality Control  Sterilization  Product release  Installation | | Servicing  Purchasing  Production  Sales  Clinical affairs | | | Quality Assurance (control of the Quality Management System)  Regulatory Affairs  Specify: | | |
| **Device designed or manufactured by audited facility** | | | | | | | |
| **Device or device family** | | **Technical Areas** | | **GMDN Codes** | **Regul.** | | **Classification** |
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|  | |  | |  | 🞏 BR | | 🞏I 🞏II 🞏III 🞏IV |
|  | |  | |  | 🞏 CA | | 🞏I 🞏II 🞏III 🞏IV |
|  | |  | |  | 🞏 JP | | 🞏I 🞏II 🞏III 🞏IV |
|  | |  | |  | 🞏 US | | 🞏I 🞏II 🞏III |
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