Auditing Organization:

AOID:

AO Assessment: [ ]  Initial [ ] Surveillance [ ] Re-recognition [ ]  Special

Witnessed Audit Reference: WA#

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

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| 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** |
|  |       |       | 🞏 AU  | 🞏I 🞏IIA 🞏IIB 🞏III |
|  |  |  | 🞏 BR | 🞏I 🞏II 🞏III 🞏IV |
|  |  |  | 🞏 CA | 🞏I 🞏II 🞏III 🞏IV |
|  |  |  | 🞏 JP | 🞏I 🞏II 🞏III 🞏IV |
|  |  |  | 🞏 US | 🞏I 🞏II 🞏III |
|  |       |       | 🞏 AU  | 🞏I 🞏IIA 🞏IIB 🞏III |
|  |  |  | 🞏 BR | 🞏I 🞏II 🞏III 🞏IV |
|  |  |  | 🞏 CA | 🞏I 🞏II 🞏III 🞏IV |
|  |  |  | 🞏 JP | 🞏I 🞏II 🞏III 🞏IV |
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|  |       |       | 🞏 AU  | 🞏I 🞏IIA 🞏IIB 🞏III |
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