|  |
| --- |
| Application Type |
| [ ]  | Initial Application | [ ]  | Transfer of Notify Body / Certification Body |

|  |
| --- |
| Applicant Organization |
| Company Name |        |
| AddressZIP CodeCityCountry |                                |
| Phone |        |
| E-mail |        |
| Website |        |

|  |
| --- |
| Contact Persons |
| Management Representative | Quality and Regulatory |
| First Name |        | First Name |        |
| Last Name |        | Last Name |        |
| Position |        | Position |        |
| Phone |        | Phone |        |
| E-mail |        | E-mail |        |

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| --- |
| Organization Size (fill Annex 1) |
| N° of Sites |        | N° Employee (FTE) |        |
| N° of Shifts |        | N° Employee / Shifts |        |

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| Did you use any consultancy services for the development and/ or maintenance of your QMS? |
| [ ]  Yes  | [ ]  No | Company Name |        |

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| --- |
| Language |
| [ ]  | French | [ ]  | English | [ ]  | German |

|  |  |
| --- | --- |
| Stage 1 audit expected by (month / year) |        |

|  |
| --- |
| Normative Reference |
| [ ]  | (EN) ISO 13485 | Version |       |
| [ ]  | Exclusion § |       | [ ]  | Non-applicability § |       |

|  |
| --- |
| Desired Scope of the certification |
| General |
| [ ]  | Design and Development | [ ]  | Production |
| [ ]  | Installation and Servicing | [ ]  | Distribution |
| Specific CSSD |
| [ ]  | Pre-disinfection | [ ]  | Transport outside of the facility |
| [ ]  | Manual Cleaning | [ ]  | Manual Disinfection |
| [ ]  | Manual Disinfection (flexible endoscope) | [ ]  | Automated Cleaning (Washer-Disinfector) |
| [ ]  | Tray Conditioning | [ ]  | Packaging Sterile Barrier System |
| [ ]  | Sterilization | [ ]  | Load Release (Washer-Disinfector + Sterilization) |
| [ ]  | Transport inside of the facility | [ ]  | Storage |
| Complementary CSSD |
| [ ]  | Instrument Management | [ ]  | Implant Management |
| [ ]  | Rental Tray Management | [ ]  | Repair Management |
| [ ]  | Providing services for a third party (doctor’s office, medical facilities not part of the organization) |
|       |

|  |
| --- |
| Processes Identification |
| [ ]  | Steam Sterilization | Temp. |       | Time |       |
| Temp. |       | Time |       |
| Temp. |       | Time |       |
| Temp. |       | Time |       |
| [ ]  | FO | Temp. |       | % |       | Time |       |
| Temp. |       | % |       | Time |       |
| Cycle description |       |
| [ ]  | ETO | Temp. |       | % |       | Time |       |
| Temp. |       | % |       | Time |       |
| Cycle description (Mix / Inert gaz?) |       |
| [ ]  | H2O2 | Temp. |       | P |       | % |       | Time |       |
| Temp. |       | P |       | % |       | Time |       |
| Cycle description |       |
| Processes Identification |
|  | Device Type | Brand / Model | In service since |
| [ ]  | Washer-Disinfector |       |       |
|       |       |
|       |       |
|       |       |
|       |       |
| [ ]  | Washer-Disinfector using chemical |       |       |
|       |       |
|       |       |
|       |       |
| [ ]  | Washer-Disinfector (endoscope) |       |       |
|       |       |
|       |       |
|       |       |
|       |       |
| [ ]  | Washer-Disinfector (endoscope) using chemical |       |       |
|       |       |
|       |       |
|       |       |
| [ ]  | Central chemical dosage station |       |       |
|       |       |
|       |       |
| [ ]  | Steam Sterilizer |       |       |
|       |       |
|       |       |
|       |       |
|       |       |
|       |       |
| [ ]  | FO |       |       |
|       |       |
| [ ]  | ETO |       |       |
|       |       |
| [ ]  | H2O2 |       |       |
|       |       |
| [ ]  | Charge Release |       |       |

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| --- |
| Special Instruments / Process |
|  |  | Model/ Type / Description |
| [ ]  | Robot |       |
| [ ]  | Instruments with limited number of possible reprocessing cycles |       |
| [ ]  | Other |       |

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| --- |
| Medical specialties that are provided by the AEMP / CSSD |
| [ ]  | Ophthalmology | [ ]  | Orthopedic / Traumatology |
| [ ]  | Gynecology | [ ]  | Visceral surgery |
| [ ]  | HNO | [ ]  | MIC |
| [ ]  | Neuro surgery | [ ]  | Heart surgery |
| [ ]  | Transplantation surgery | [ ]  |       |
|  | By my signature, I certify that I am an authorized representative of the applicant organization and that the provided details are accurate and complete. |
|  | Name:        | Position:        |
|  | Location:        | Date:        |
|  | Signature:  |

|  |
| --- |
| Annex 1 - List of Sites |
| [ ]  | [ ]  | [ ]  |
| Management / Admin | Quality & Regulatory | Production |
| Company Name |        | Contact |        |
| AddressZIP CodeCityCountry |                                |
| Phone |        | E-mail |        |

|  |
| --- |
| Annex 1 - List of Sites |
| [ ]  | [ ]  | [ ]  |
| Management / Admin | Quality & Regulatory | Production |
| Company Name |        | Contact |        |
| AddressZIP CodeCityCountry |                                |
| Phone |        | E-mail |        |

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| --- |
| Annex 1 - List of Sites |
| [ ]  | [ ]  | [ ]  |
| Management / Admin | Quality & Regulatory | Production |
| Company Name |        | Contact |        |
| AddressZIP CodeCityCountry |                                |
| Phone |        | E-mail |        |