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

|  |  |
| --- | --- |
| Applicant Organization | |
| Company Name |  |
| Address  ZIP Code  City  Country |  |
| 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 |  |

|  |  |  |  |
| --- | --- | --- | --- |
| 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 |

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

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| --- | --- | --- | --- | --- | --- |
| 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) | | |
|  | | | |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 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 | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
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|  | | | | |  | | | | | |
|  | | Washer-Disinfector using chemical | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | Washer-Disinfector (endoscope) | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | Washer-Disinfector (endoscope) using chemical | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | Central chemical dosage station | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | Steam Sterilizer | | | |  | | | | |  | | | | | |
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|  | | | | |  | | | | | |
|  | | FO | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | ETO | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | H2O2 | | | |  | | | | |  | | | | | |
|  | | | | |  | | | | | |
|  | | Charge Release | | | |  | | | | |  | | | | | |

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

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 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: | | | | |

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| Annex 1 - List of Sites | | | | | |
|  | |  | |  | |
| Management / Admin | | Quality & Regulatory | | Production | |
| Company Name |  | | Contact | |  |
| Address  ZIP Code  City  Country |  | | | | |
| Phone |  | | E-mail | |  |

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| --- | --- | --- | --- | --- | --- |
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| Annex 1 - List of Sites | | | | | |
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| Company Name |  | | Contact | |  |
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| Phone |  | | E-mail | |  |