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| **Certificate holder:**  Complete and legal name of manufacturer (Please verify correct version and consistency with data in General Agreement, Application and Contract) | (Manufacturer’s name & legal form, e.g. GmbH, Ltd., Inc.) | | |
| (street) | | |
| (town, state, ZIP code, country) | | |
|  | (contact person, phone #, email) | | |
| **Site 1** | (site name including legal form if different than HQ)  (site address (street, town, state, ZIP code, country)) | | |
| **Site 2** | (site name including legal form if different than HQ)  (site address (street, town, state, ZIP code, country)) | | |
| **Site 3** | (site name including legal form if different than HQ)  (site address (street, town, state, ZIP code, country)) | | |
| **Site 4** | (site name including legal form if different than HQ)  (site address (street, town, state, ZIP code, country)) | | |
| **Requested certificates:**  (Please use one separate Certificate  Print Request per Directive \*) | 93/42/EEC (MDD)\*  90/385/EEC (AIMDD)\*  98/79/EC (IVDD)\*  EN ISO 13485  ISO 13485 (SCC accreditation)  ISO 13485 under CMDCAS  EN ISO 9001  ISO 9001 (SCC accreditation)  MDSAP | | |
|  | Participation in TCP (Technical Cooperation Programme) Taiwan | | |
| **Reason for Request:** (Please check all that apply) | Certification / Recertification Audit  change in the scope of certification  (e.g. change in scope, additional location)  Additional certificate(s), as copies (Please indicate amount)  Additional language(s) (Please provide translation(s))  Change of name, legal status (e.g. Inc., Ltd.) or address of company (Please submit new General Agreement, Application and Contract, and in case of certification according to directives revised Application(s))  Error/Clarification on certificate (please describe in the comments section below)  Other significant changes not mentioned above (please attach Significant Change Notification)  Others (please describe in the comments section below) | | |
| (Please click to enter comments) | | | |
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| Location, date | |  | Name & signature of the company’s representative | |
|  | |  |  | |
| Location, date | |  | Name & signature of lead auditor | |

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| **Certificate according to Directive** | | | | | |
| **93/42/EEC (MDD)** | | **90/385/EEC (AIMDD)** | | **98/79/EC (IVDD)** | |
| **Language of Certificate: English** | | | | | |
| **Conformity Assessment procedure:**   |  | | --- | | **Full quality assurance system** (MDD Annex II excluding 4 or AIMDD Annex 2  without 4 or IVDD Annex IV excluding 4 and 6)  **Production quality assurance** (MDD Annex V or AIMDD Annex V or IVDD Annex VII excluding 5)  **Product quality assurance** (only MDD Annex VI) | | | | **Scope:** Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards  (e.g. non-active orthopedic and rehabilitation devices) | | |
| Please list **additional sites** covering the activities production and/or design and development | | | **Additional sites (see previous page):** (e.g. site 1, site 2) | | |
| **Other languages from the European Community:** | | | | | |
| **Language:**  **Deutsch** | | | **Scope: For each additional language** please list specific product groups covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  z.B. nicht-aktive orthopädische und Rehabilitations-Produkte) | | |
| **Language:**  (Please indicate an additional language) | | | (e.g. non-active orthopedic and rehabilitation devices) | | |
| **Language:**  (Please indicate an additional language) | | | (e.g. non-active orthopedic and rehabilitation devices) | | |
| (Please click to enter comments) | | | |

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| **Certificate according to EN ISO 13485 and/or ISO 13485 (SCC accredited)** |

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| **Scope of the main certificate: (check all activities within the scope of the quality management system)** | | |
| **Design and Development**  **Manufacture**  **Distribution**  **Installation**  **Service**  \*Not applicable for ISO 13485 (SCC accredited) | **Sterilization\* Sterilization Method:** (Please indicate method)  **Reprocessing (KRINKO/BfArM)\***  **Others\*** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) | |
|  |  |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards: (e.g. non-active orthopedic and rehabilitation devices) | | |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution**  **Installation**  **Service**  \*Not applicable for ISO 13485 (SCC accredited) | **Sterilization\* Sterilization Method:** (Please indicate method)  **Reprocessing\* (KRINKO/BfArM)**  **Administration**  **Others\*** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |
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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution**  **Installation**  **Service**  \*Not applicable for ISO 13485 (SCC accredited) | **Sterilization\* Sterilization Method:** (Please indicate method)  **Reprocessing\* (KRINKO/BfArM)**  **Others\*** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Certificate according to EN ISO 13485 and/or ISO 13485 (SCC accredited)** |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution**  **Installation**  **Service**  \*Not applicable for ISO 13485 (SCC accredited) | **Sterilization\* Sterilization Method:** (Please indicate method)  **Reprocessing\* (KRINKO/BfArM)**  **Administration**  **Others\*** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |
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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution**  **Installation**  **Service**  \*Not applicable for ISO 13485 (SCC accredited) | **Sterilization\* Sterilization Method:** (Please indicate method)  **Reprocessing\* (KRINKO/BfArM)**  **Administration**  **Others\*** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |
| **Additional language from the European Community**  **Language:** (Please name language)  (Please indicate below the translation for each applicable scope, e.g. “Distribution”) | |
| **Design and Development:** (Please indicate translation)  **Manufacture:** (Please indicate translation)  **Distribution:** (Please indicate translation)  **Installation:** (Please indicate translation)  **Service:** (Please indicate translation)  **Sterilization:** (Please indicate translation)  **Sterilization Method:** (Please indicate method)  **Reprocessing (KRINKO/BfArM):** (Please indicate translation)  **Others** Please click to enter data (only applicable for special activities, which are not covered by the above mentioned terms) | |
| For each additional language please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards: (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Certificate according to ISO 13485:2003 under CMDCAS** | |
| **Language of certificate:** | **Scope:** |
| **English** | **Design and Development**  **Design**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** |
| Please define the scope of the quality management system. For assistance, please refer to examples included in GD207. | (e.g. Computed Tomography Systems, X-Ray Systems and Magnetic Resonance Imaging Systems) |
| **Declaration of intent to sell** (might be applicable only at first time certification)  As a signing authority for the company, I declare the intent to legally sell medical devices in Canada, as defined in the Food and Drugs Act, and to obtain all required Medical Device Licenses as required by the Medical Devices Regulations.  The company intends to sell devices that are classified as *(check all appropriate)*:  Class II  Class III  Class IV  medical devices according to the classification rules found in the *Medical Devices Regulations (Schedule 1).*  I attest on behalf of the company that said company possesses a current copy of the *Medical Devices Regulations*, understands the applicability of these regulations to its intent to sell in Canada and has incorporated in its quality system the relevant sections of Part 1 of these regulations as they apply to the devices identified in Part B.  By signing this, I attest that I understand and accept that the registrar with which I contract will verify the ongoing accuracy of this information on an annual basis and will act accordingly should this information change. I also understand that should I fail to obtain a medical device license before my registration expires, I am subject to a review of applicability by Health Canada. I also understand that in such circumstances my registrar may be instructed by Health Canada not to renew my certification under CMDCAS. | |
| (Please click to enter Comments) | |

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| **Certificate according to ISO 13485:2003 under CMDCAS** |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution** | **Administration**  **Installation**  **Service** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution** | **Administration**  **Installation**  **Service** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution** | **Administration**  **Installation**  **Service** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture**  **Distribution** | **Administration**  **Installation**  **Service** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Certificate according to EN ISO 9001 and/or ISO 9001** | |
| **Language of the certificate:** | **Scope:** |
| **English** | (e.g. design and development, manufacture and distribution of infusion pumps) |
| **German** | (z.B. Design und Entwicklung, Herstellung und Vertrieb von Infusionspumpen) |
| **Language:**  (Please indicate the language) | (Please translate the scope for each additional language)  Note: For ISO 9001 under SCC accreditation, only English and French are allowable. |
| (Please click to enter Comments) | |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Certificate according to EN ISO 9001 and/or ISO 9001** |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products; e.g. from NBOG 2009-3, CEN/TR 15133, or technical standards:  (e.g. non-active orthopedic and rehabilitation devices) | |

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| **Certificate according to MDSAP** |

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| **Scope of the main certificate: (check all activities within the scope of the quality management system and the applicable jurisdictional area in which the devices are being marketed and sold)** | | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **USA**  **Japan**  **Canada**  **Other\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Brazil**  **Australia**  **Design and Development**  **Design and Development**  **Design and Development** | |
|  |  |
| Please list **specific product groups** covering your individual products (e.g. non-active orthopedic and rehabilitation devices): | | |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products (e.g. non-active orthopedic and rehabilitation devices): | |
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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products (e.g. non-active orthopedic and rehabilitation devices): | |

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| **Certificate according to MDSAP** |

**Additional sites:**

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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products (e.g. non-active orthopedic and rehabilitation devices): | |
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| **Site #:** (site # as indicated on page 1) **Check all activities in the scope of this site:** | |
| **Design and Development**  **Manufacture (or Production)**  **Distribution**  **Installation**  **Service** | **Administration** |
| Please list **specific product groups** covering your individual products (e.g. non-active orthopedic and rehabilitation devices): | |