Manufacturer: «Firmenname», «Strasse», «Ort»

Please specify in this list OEM-Manufacturers (only for directive procedures) and suppliers from which you obtain essential components/materials, and suppliers which carry out significant production steps. These statements are to be limited to medical devices Class I (sterile), I (measurement function), IIa, IIb and III as well as to In-vitro-diagnostic medical devices of list A and B as well as products for self-testing.

(According to NBOG BPG 2010-1 (<http://www.doks.nbog.eu/Doks/NBOG_BPG_2010_1.pdf>) you have to classify suppliers of materials, components or services as critical, if they can have effects on the safety and performance of the products.)

| No. | Suppliers / OEM-Manufacturers(Name and complete address) | Concerned Product | Activities / materials / components | Certified according to (Please attach appropriate copies of certificates) |
| --- | --- | --- | --- | --- |
|  |       |       | [ ] Sub-contract manufacturing \*:      [ ] OEM-Manufacturer (OEM-Case Ia/Ib, EK-Med decision 3.9B16)[ ] Cleaning/Packing[ ] Quality assurance[ ] Sterilization \*:      [ ] Final Packaging / Labelling / Storage[ ] Materials / Components:      [ ] Others\*:       | [ ]  93/42/EEC[ ]  Reg 2017/745[ ]  98/79/EC[ ]  Reg 2017/746[ ]  ISO 13485[ ]  ISO 9001[ ]  no certification |
|  |       |       | [ ]  Sub-contract manufacturing \*:      [ ]  OEM-Manufacturer (OEM-Case Ia/Ib, EK-Med decision 3.9B16)[ ]  Cleaning/Packing[ ]  Quality assurance[ ]  Sterilization \*:      [ ]  Final Packaging / Labelling / Storage[ ]  Materials / Components:      [ ]  Others\*:       | [ ]  93/42/EEC[ ]  Reg 2017/745[ ]  98/79/EC[ ]  Reg 2017/746[ ]  ISO 13485[ ]  ISO 9001[ ]  no certification |
|  |       |       | [ ]  Sub-contract manufacturing \*:      [ ]  OEM-Manufacturer (OEM-Case Ia/Ib, EK-Med decision 3.9B16)[ ]  Cleaning/Packing[ ]  Quality assurance[ ]  Sterilization \*:      [ ]  Final Packaging / Labelling / Storage[ ]  Materials / Components:      [ ]  Others\*:       | [ ]  93/42/EEC[ ]  Reg 2017/745[ ]  98/79/EC[ ]  Reg 2017/746[ ]  ISO 13485[ ]  ISO 9001[ ]  no certification |

\* Please specify the affected production steps and used production technologies / method of sterilization / materials / activities

|  |  |  |
| --- | --- | --- |
|       |  |       |
| (Place, Date) |  | (Name, Signature) |

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