**List of the standards applied in full or in part**

Investigational device *(name, size, model.)*:

Manufacturer:

Date:

*According to § 4 in Executive Order No. 292 of 19 March 2010, and EN ISO 14155 Annex B 6a, a list of standards applied in full or in part for the investigational device, shall be part of the Investigators Brochure.*

| **Standard** | **Compliance to standard** |
| --- | --- |
| Title | Identifier | Version / year | Full | Partial Description of all deviations and of the alternative solutions adopted to meet the Essential Requirements of directive 90/385/EEC or 93/42/EEC |
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| *i.e.** *Clinical investigation of medical devices for human subjects- Good clinical practice*
 | *EN ISO14155* | *2012* |[x] [ ]   |
| * *Symbols for use in the labelling of medical devices*
 | *EN 980* | *2008* |[x] [ ]   |
| * *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*
 | *EN ISO 10993-1* | *2009* |[x] [ ]   |
| * *Medical devices - Application of risk management to medical devices*
 | *EN ISO 14971* | *2012* |[x] [ ]   |
| * *Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems*
 | *EN/IEC 60601-1-1* | *2000* |[x] [ ]   |