11 ES prohlášení o shodě (CE declaration of conformity)

..11.1 Prohlášení o shodě modulu InspectLife

EC Declaration of Conformity
and
Declaration of Compatibility

We, MEDIWARE a.s. declare under our sole responsibility that the following active medical device class I (software) is in conformity with Annex 7 of Directive 93/42/EC.

We have verified the mutual compatibility of medical devices assembled according to the manufacturer's instructions and performed the operation to operate according to these instructions.

We wrapped a system or kit of medical devices and are connected to the corresponding user information, including instructions from individual manufacturers of medical devices.

Our work in setting up medical device meets the requirements of ISO 13485 and Annex II to Directive 93/42.

Product: Inspect*Life* modul Telemonitoring of blood pressure

Models: **1**

The following harmonized standards were used to assess compliance with Directive 93/42/EEC:

- EN ISO 14971:2012 Medical devices – Application of risk management to medical devices
- EN 1041:2009 Information supplied by the manufacturer of medical devices
- EN ISO 62304:2007 Medical device software - Software life-cycle processes
- EN ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes

The following test reports and certificates were used to assess with Directive 93/42/EEC

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16. 12. 2014
Date

Person authorized to sign