European Declaration of Conformity

We,

Spiro Medical AS
Nattlandsveien 8
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Norway
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declare under our sole responsibility that the product

ApneaGraph Spiro, including
EL-0019 Torso Unit,
EL-0021 Neck Unit,
EL-0020 Wrist Unit,
EL-0018 Cannula Unit,
EL-0030/31/32/33 Single or Multiple Use Catheter Unit

to which this declaration relates, is in conformance with the followings standards:

- ANSI/AAMI ES60601-1:2005/A1:2012 Issued: 2012/08/20 Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance, Amendment 1.
- IEC 60601-1-6 Issued: 2013/10/29 Ed. 3.1 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- IEC 62366 Issued: 2014/01/28 Ed. 1.1 Medical Devices – Application of Usability Engineering to Medical Devices.
- ANSI/AAMI HA60601-1-11:2011 Issued: 2011/11/11 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- CSA C22.2#60601-1-11 Issued: 2011/07/01 Medical Electrical Equipment – Part 1-11: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.

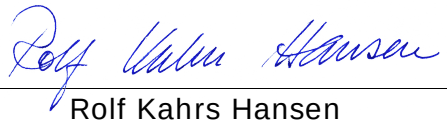
- CSA-C22.2 No. 60601-1:14, Third Edition Issued: 2014/03/01 – Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance.
- CSA-C22.2 No. 60601-1-6:11 Issued: 2008/12/01 Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability.
- UL 60601-1 Issued: 2003/04/25 Ed: 1 Rev: 2006/04/26 Medical Electrical Equipment – Part 1: General Requirements for Safety.
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances. Requirements and Tests.

The object of the declaration described above is in conformity with the relevant Community harmonisation legislation: Directive 93/42/EEC (MDD) and Directive 2011/65/EU (RoHS).

The notified body is DNV GL Nemko Presafe AS, Notified Body 2460.

The Technical Construction File is maintained at our premises and we are the authorized representative within the EU Community.

Date 09.10.2017
Place Bergen, Norway



Rolf Kahrs Hansen
Technical Director