11 REGULATORY INFORMATION

11.1 Classification EU

In accordance with MDD 93/42/EEC: Class IIa medical device

EN60601-1: Internally powered equipment

11.1.1 Declaration of Conformity

We herewith declare under our sole responsibility that the product listed below is in conformity with the provisions of the Council Directive 93/42/EEC of 14 June 1993 (and the Finnish national laws 1505/94 and 1506/94) concerning medical devices. When used with external evaluation software this declaration of conformity is valid for the Faros hardware.

Trade Name: Faros Product Family

Model(s): Faros 180

Faros 360

MDD Classification: Class IIa

Following standards were used to meet requirements:

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical Electrical Equipment - Part 1 General Requirements for Basic Safety and Essential Performance.
- IEC 60601-1-2: 2014, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-2-47:2012, Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems.
- IEC 60601-1-11:2015+AMD1:2020, 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.
- IEC 62366-1:2015+AMD1:2020, Medical devices -- Application of usability engineering to medical devices.
- IEC 62304:2006, Medical device software -- Software lifecycle processes.
- According to the manufacturer of the Bluetooth modules: The Bluetooth modules meet the requirements of the EMC Directive 89/336/EEC as amended by Directives 92/31/EEC and 93/68/EEC within CE marking requirement.