EC Declaration of Conformity for the IVD Medical Device: BluBox

Developed and Manufactured by:
BluSense Diagnostics ApS
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10. 7. 2018

Hereby, BluSense Diagnostics ApS declare that the BluBox IVD medical device, complies with all essential requirements (Annex I) of the DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices.

Product Name: BluBox

Product Model: D6.0

Catalogue Number: 60BB01

Classification: BluBox fallS under the IVD Directive (98/79/EC), Article 9, section 1, allowing BluSense Diagnostics ApS to prepare the technical documentation and ensure that the manufacturing process follows the principles of quality assurance as set out in the IVD Directive, and to draw up a Declaration of Conformity covering the devices concerned, i.e. BluBox, without passing a Conformity Assessment by a Notified Body.

GMDN code: 61726

GMDN term: Multiplex analyser IVD, point-of-care

Quality System: BluSense Diagnostics ApS a has Quality Management System in place based on DS/EN ISO 13485:2016, Certified by BSI in Certificate of Registration Number: MD 663350 (Effective date: 2017-06-22; Expiry date: 2020-06-21) for the following scope: Design, development, manufacture and distribution of IVD analysers and reagents for detection of biomarkers to diagnose diseases.

List of Applicable International Standards

Version of Standard	Full Title
DS/EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
DS/EN ISO 14971: 2012	Medical Devices – Application of Risk Management to Medical Devices
IEC 62366-1:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
EN 61010-2-101:2015	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6:2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

EN 62304:2006 + AC:2008	Medical device software - Software life-cycle processes
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 18113-1: 2009	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use

This Declaration of Conformity is issued under Sole Responsibility of BluSense Diagnostics ApS.

Name: Filippo Bosco

Title: CEO

Copenhagen, July 6th, 2018.

Date and authorized signature

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