EC Declaration of Conformity for the IVD Medical Device:

Developed and Manufactured by:
BluSense Diagnostics ApS
Fruebjergvej 3,
DK-2100 København Ø

Hereby, BluSense Diagnostics ApS declares that the IVD medical device listed below complies with all essential requirements (Annex I) of the IVD Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 on In Vitro medical devices.

The IVD medical device falls under Article 9, section 1 in the abovementioned Directive, which allows the Manufacturer, BluSense Diagnostics ApS, to self-declare conformance to Annex 1 of the Directive.

Product Name: ViroTrack Sero COVID-19 Total Ab

Product Model: N/A

Classification: Others (See below)

Catalogue Number: 03VTS02-25

Classification: The above-listed product 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, without passing a conformity assessment by a Notified Body.

GMDN code: 65528

GMDN term: A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of total antibodies to severe acute respiratory syndrome-associated coronavirus 2 (SARS-CoV-2), the causative agent of coronavirus disease (COVID-19), in a clinical specimen within a short period, relative to standard laboratory testing procedures, using a magnetic immunoassay method. This test is commonly used in the laboratory or in point-of-care analyses. It is not intended to be used for self-testing.

Quality System: BluSense Diagnostics ApS has a Quality Management System in place based on EN ISO 13485:2016, Certified by BSI in Certificate of Registration Number: MD 663350 (Effective date: 2020-06-22, Expiry date: 2023-06-21) for the following scope: Design, development, manufacture, and distribution of IVD analyzers and reagents for detection of biomarkers to diagnose diseases.

List of Applicable International Standards

Reference date	Title
Standard	
98/79/EC	DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices
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
DS/EN ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
IEC 62366-1:2015	Medical Devices – Part 1: Application of Usability Engineering to Medical Devices
BS EN 13641:2002	Elimination or reduction of risk of infection related to in vitro diagnostic reagents
EN ISO 23640: 2015	In Vitro Diagnostic Medical Devices – Evaluation of Stability of In Vitro Diagnostic reagents
BS EN 13612: 2002	Performance evaluation of In Vitro Diagnostics Medical Devices
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
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements
EN ISO 18113-2: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

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

Name: Robert Burger

Title: Chief Operating Officer

2021-May-20

Date and authorized signature

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Signatory Table

Action Name	User Name	Title	Signature Date
Send for Review (Written By)	Alex Espinoza	QA/RA Deputy Manager	20-May-2021 18:08 (GMT+2)
Review	Robert Burger	COO	21-May-2021 09:42 (GMT+2)
Send for Approval	Alex Espinoza	QA/RA Deputy Manager	21-May-2021 10:10 (GMT+2)
Approve	Robert Burger	COO	21-May-2021 10:19 (GMT+2)
QA Approval - Skip Training	Robert Burger	COO	21-May-2021 10:39 (GMT+2)