

CERTIFICATE

Number: **3820269**

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Abbott Point of Care, Inc.

100 and 200 Abbott Park Road

Abbott Park, IL 60064

United States Of America

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

The design, development, manufacture, service and distribution of near patient in vitro diagnostic medical devices, including in vitro diagnostic cartridges, controls, analyzers/software, and accessories used in the diagnosis and management of disease status (cardiac markers, blood analytes, blood components, blood gases and coagulation), and the installation of product software.

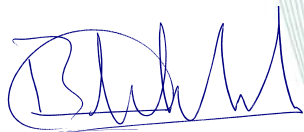
Certificate expiry date: 04 January 2025

Certificate effective date: 14 January 2022

Certified since: 10 January 2019

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.A. van Vugt
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: **3820269**

The management system of the organization(s) and/or location(s) of:

Abbott Point of Care, Inc.

100 and 200 Abbott Park Road
Abbott Park, IL 60064
United States Of America

Certified organization(s) and/or locations:

Abbott Point of Care Canada Limited
185 Corkstown Road
Nepean Ontario K2H 8V4
Canada

Abbott Point of Care, Inc.
400 College Road East
Princeton NJ 08540
USA

Abbott Point of Care, Inc.
2 Research Way,
Princeton NJ 08540

Different scope:

Manufacture of biosensors microfabricated into silicone chips for use as a component in the In Vitro Diagnostic Disposable Cartridge. Design, manufacture and distribution of In Vitro Diagnostic Disposable Cartridges and Controls used in the diagnosis and management of disease status (cardiac markers, blood analytes, blood gases and coagulation).

Design, manufacture, service and distribution of In Vitro Diagnostic analyzer, product software and accessories, and the installation of product software.

Complaint handling and Technical Service.

Addendum expiry date: 04 January 2025
Addendum effective date: 14 January 2022