

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

Registration No.: SX 2673511-1

Certificate Holder: BioPorto Diagnostics A/S
Tuborg Havnevej 15, st.
2900 Hellerup
Denmark

Scope: Design and development, manufacture and distribution of immunological-based in-vitro diagnostic reagent used in the diagnosis of immune status and renal disorders.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.

Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

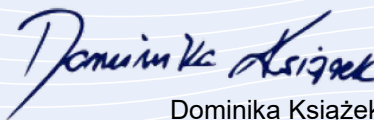
Report No.: 84984865-30

Effective date: 2025-08-06

Expiry date: 2028-01-06

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This certificate can be validated on <https://www.certipedia.com>



Dominika Książek
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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