Certificate

Certificate No.:	MD 2673511-1-1
Manufacturer:	**BioPorto Diagnostics A/S** Tuborg Havnevej 15, st. 2900 Hellerup Denmark
REPs Facility ID:	F002670
Certification criteria:	ISO 13485:2016 Canada Medical Devices Regulations – Part 1 – SOR 98/282, United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D
Scope:	Design and development, manufacture and distribution of immunological-based in-vitro diagnostic reagent used in the diagnosis of immune status and renal disorders.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.:	84984865-30
Issue Date:	2025-08-06
Effective Date:	2025-08-06
Expiry Date:	2028-01-16

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

Certification officer: Dominika Książek
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com
or calling 1-888-743-4652.

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