

Certificate

Certificate No.: MD 2673511-1-2

Manufacturer: **BioPorto Diagnostics A/S**
Tuborg Havnevej 15, st
2900 Hellerup
Denmark

REPs Facility ID: F008404

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: The design and development, manufacture and distribution of immunological-based in-vitro diagnostic reagent used in the diagnosis of immune status and renal disorders. [®]

TÜV Rheinland

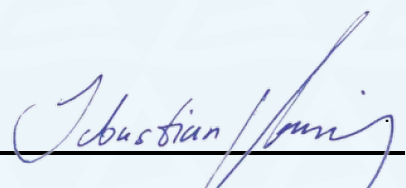
TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject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

Project No.: 84988881-10

Issue Date: 2026-02-23

Effective Date: 2026-02-23

Expiry Date: 2028-01-16



Certification officer: Sebastian Mniszek
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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The scope of certification also covers the following sites:

No.	Location	Scope
/01	BioPorto Diagnostics A/S Tuborg Havnevej 15, st 2900 Hellerup, Denmark REPs Facility ID: F008404	Design and Development, Manufacture and Distribution
/02	BioPorto A/S Tuborg Havnevej 15, st 2900 Hellerup, Denmark REPs Facility ID: F008404	Administration
/03	BioPorto Diagnostics Inc 117 Kendrick Street, Suite 300 Needham MA 02494, USA REPs Facility ID: F008781	Design and Development



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