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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 082277 0008 Rev. 04

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

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Immunological-Based In-Vitro Diagnostic Reagents Used in the Diagnosis of Immune Status and Renal Disorders**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Health Canada, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 082277 0008 Rev. 04
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002670**
Report No.: **713338072**
Effective Date: **2025-01-17**
Expiry Date: **2028-01-16**

Date of Issue: 2024-11-14

(Renee Walker)
Director, US Certification Body, MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Canada
- Medical Device Regulations – Part 1- SOR 98/282

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies): **BioPorto Diagnostics A/S**
Tuborg Havnevej 15, st., 2900 Hellerup, DENMARK

Facility Scopes: Design, Development, Production and Distribution
of Immunological-Based In-Vitro Diagnostic Reagents
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