ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 082277 0007 Rev. 02

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

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

See Scope of Certificate

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**

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 082277 0007 Rev. 02

Report No.: 713338072

Valid from: 2025-01-07
Valid until: 2028-01-06

Date, 2024-09-26

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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