



Certificate

No. Q5 082277 0007 Rev. 01

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):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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 and certification regulation of 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. 01

Report No.: 713224816

Valid from: 2022-01-07

Valid until: 2025-01-06

Date, 2021-12-13



Christoph Dicks

Head of Certification/Notified Body