



# Certificate

No. Q5 082277 0007 Rev. 00

**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

**Certification Mark:**



**Scope of Certificate:** **Design & development, production, marketing and sales of antibody-based in vitro diagnostic assays**

**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). See also notes overleaf.

**Report No.:** 713135204

**Valid from:** 2019-01-07

**Valid until:** 2022-01-06

**Date,** 2018-12-20

Stefan Preiß

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFIKAT ◆ CERTIFICATE