

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2673511-1  
Certificate Holder: BioPorto Diagnostics A/S  
Tuborg Havnevej 15, st.  
2900 Hellerup  
Denmark  
Scope: Design and development, manufacture and distribution of immunological-based in-vitro diagnostic reagent used in the diagnosis of immune status and renal disorders.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 84988881-10  
Effective date: 2026-02-23  
Expiry date: 2028-01-06  
Issue date: 2026-02-23  
Replaces certificate SX 2673511-1 issued 2025-08-06

This certificate can be validated on <https://www.certipedia.com>

  
Jaroslaw Rodak  
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The scope of certification also covers the following sites:

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

This certificate can be validated on <https://www.certipedia.com>