

# Certificate

## Quality Management System

**EN ISO 13485:2016**

**EN ISO 13485:2016/AC:2018**

**EN ISO 13485:2016/A11:2021**

Registration No.: SX 1936892-1  
Certificate Holder: TOSOH EUROPE NV  
Transportstraat 4  
3980 Tessenderlo-Ham  
Belgium

Scope: Design, development and manufacturing of in vitro diagnostic reagents and quality controls used in the fields of cancer, cardiac, metabolic and thyroid markers, disease status, endocrine and metabolic disorders, fertility testing and prenatal screening.  
Distribution, installation and service of invitro diagnostic reagents, assays, quality controls and kits, as well as related diagnostic instruments.

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.: 1175489-100  
Effective date: 2025-02-12  
Expiry date: 2028-02-11  
Issue date: 2025-02-04  
Replaces certificate SX 1936892-1 issued 2023-10-31



Dr. Matthias Fischer  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o TOSOH EUROPE NV Transportstraat 4 3980 Tessenderlo-Ham Belgium	Design and development, manufacture, distribution, installation and service
/02	c/o Tosoh Europe NV Im Leuschnerpark 4 64347 Griesheim Germany	Distribution, installation and service
/03	c/o Tosoh Europe NV 9 rue des Colones 75002 Paris France	Distribution, installation and service
/04	c/o Tosoh Bioscience Ltd. 10 Queen Street Place London EC4R 1AG United Kingdom	Distribution, installation and service  c/o Business Address: Lytchett House Wareham Road, 13 Freeland Park, Dorset, Poole, BH16 6FA United Kingdom
/05	c/o Tosoh Bioscience SRL Via Chivasso, 15/A Cascine Vica 10098 Rivoli-Torino Italy	Distribution, installation and service

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