Certificate

Digitally signed by Baltag Lilian
Date: 2025.11.27 11:23:03 EET
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Location: Moldova
MOLDOVA EUROPEANĂ

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

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

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

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

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

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 Colonnes 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 HouseWareham Road, 13Freeland 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

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

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Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1910005**

Certificate Holder: **TOSOH EUROPE NV**
Transportstraat 4
3980 Tessenderlo-Ham
Belgium

including the locations according to annex

Scope: Design, development and manufacturing of in-vitro diagnostic reagents and quality controls, used in the fields of tumor, cardiac, metabolic and thyroid markers, disease status, endocrine and metabolic disorders, fertility testing and prenatal screening.
Sales, marketing, distribution and service of in-vitro diagnostic reagents, assays, quality controls and kits, as well as related diagnostic instruments. Sales, marketing, distribution, customer support and service for media, instruments and detectors for analytical and preparative liquid chromatography.

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2025-02-12 until 2028-02-11.
First certification 1999

2025-02-05

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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