

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 1936892-1

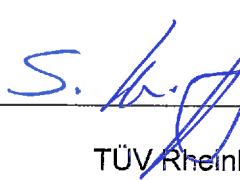
Organization: TOSOH EUROPE NV
Transportstraat 4
3980 Tessenderlo
Belgium

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.: 1096892-40
Effective date: 2022-02-12
Expiry date: 2025-02-11
Issue date: 2022-02-10




Dipl.-Ing. Sven Hoffmann
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany



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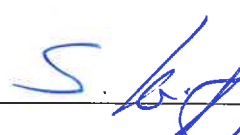
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Belgium

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o TOSOH EUROPE NV Transportstraat 4 3980 Tessenderlo 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 Immeuble Cap Constellation - Batiment A 3 Boulevard Henri Ziegler 31700 Blagnac France	Distribution, installation and service
/04	c/o Tosoh Bioscience Ltd. 100 Longwater Avenue, Green Park Reading RG2 6GP United Kingdom	Distribution, installation and service

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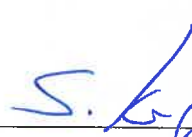
The scope of certification also covers the following:

/05 c/o Tosoh Bioscience SRL
Via Chivasso, 15/A Cascine Vica
10098 Rivoli-Torino
Italy

Distribution, installation and service

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