

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

TOSOH EUROPE NV
Transportstraat 4
3980 Tessenderlo
Belgium

has established and applies a quality management system for medical devices
for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2019-08-16
Certificate Registration No.: SX 60141888 0001
An audit was performed. Report No.: 60270723 001
This Certificate is valid until: 2022-02-11

Certification Body



Date 2019-08-16



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60141888 0001
Report No.: 60270723 001

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 and service of in-vitro diagnostic reagents, assays, quality controls and kits, as well as related diagnostic instruments.

Additional sites included:

Tosoh Europe NV
Im Leuschnerpark 4
64347 Griesheim, Germany


Activities:

Distribution and service of in vitro diagnostic devices

Certification Body



Date: 2019-08-16


Dipl.-Ing. Sven Hoffmann

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60141888 0001
Report No.: 60270723 001

Organization: TOSOH EUROPE NV
Transportstraat 4
3980 Tessenderlo
Belgium

Scope:

Additional sites included:
Tosoh Europe NV
Immeuble Cap Constellation - Batiment A
3 Boulevard Henri Ziegler
31700 Blagnac, France
Activities:
Distribution and service of in vitro diagnostic devices

Tosoh Bioscience Ltd.
100 Longwater Avenue, Green Park
Reading, RG2 6GP, United Kingdom
Activities:
Distribution and service of in vitro diagnostic devices

Tosoh Bioscience SRL
Via Chivasso, 15/A Cascine Vica
10098 Rivoli-Torino, Italy
Activities:
Distribution and service of in vitro diagnostic devices

Certification Body



Date: 2019-08-16


Dipl.-Ing. Sven Hoffmann