

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
TOSOH Corporation
Shiba-Koen First Building
3-8-2 Shiba, Minato-ku
Tokyo
105-8623 Japan

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

**Design and development, manufacture, distribution,
installation and service of in vitro diagnostic
medical devices
(see attachment for products and sites included)**

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: 2019-08-31
Certificate Registration No.: SX 60142320 0001
An audit was performed. Report No.: 12031283 012
This Certificate is valid until: 2022-08-30

Certification Body



Date 2019-08-29


M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60142320 0001
Report No.: 12031283 012

Organization: TOSOH Corporation
Shiba-Koen First Building
3-8-2 Shiba, Minato-ku
Tokyo
105-8623 Japan

Scope: Immunoassay analyzers, Glycohemoglobin analyzers,
Molecular testing analyzers, Catecholamine analyzers,
High performance liquid chromatography analyzers, Microtitre
plate readers, Reagents, Calibrators, Controls, Buffers,
Columns, Peripherals, Consumables, Parts, Accessories

Certification Body



Date: 2019-08-29


M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60142320 0001
Report No.: 12031283 012

Organization: TOSOH Corporation
Shiba-Koen First Building
3-8-2 Shiba, Minato-ku
Tokyo
105-8623 Japan

Scope:

Sites included:

Tosoh Corporation Bioscience Division Planning & Business
Development / Sales / Marketing
Shiba-koen First Building, 3-8-2, Shiba, Minato-ku,
Tokyo, 105-8623 Japan

Scope:

Distribution of in vitro diagnostic medical devices

Research & Development / Customer Support Center
2743-1, Hayakawa, Ayase, Kanagawa 252-1123, Japan

Scope:

Design and development, manufacture and service of
in vitro diagnostic medical devices

Certification Body



Date: 2019-08-29

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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Organization: TOSOH Corporation
Shiba-Koen First Building
3-8-2 Shiba, Minato-ku
Tokyo
105-8623 Japan

Scope:

Sites included:

Separation Media Production / Research & Development
4560, Kaisei-cho, Shunan, Yamaguchi 746-8501 Japan

Scope:

Design and development and manufacture of
in vitro diagnostic medical devices

Osaka Branch Bioscience Group

4-4-9, Kouraihashi, Chuo-ku, Osaka, Osaka, 541-0043 Japan

Scope:

Distribution of in vitro diagnostic medical devices

Certification Body



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Organization: TOSOH Corporation
Shiba-Koen First Building
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Tokyo
105-8623 Japan

Scope:

Sites included:

Nagoya Branch Bioscience Group
1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan

Scope:

Distribution of in vitro diagnostic medical devices

Sendai Branch

1-11-1, Hon-cho, Aoba-ku, Sendai, Miyagi 980-0014, Japan

Scope:

Distribution of in vitro diagnostic medical devices

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Scope:

Sites included:

Fukuoka Branch
1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka 810-0001, Japan

Scope:

Distribution of in vitro diagnostic medical devices

Tosoh Techno-System Inc. Tokyo Service Station
2-5-10, Shiba, Minato-ku, Tokyo 105-0014, Japan

Scope:

Installation and Service of in vitro diagnostic medical devices

Tosoh Techno-System Inc. Hokkaido Service Station
Minami 1 Jo Nishi 7-20-1, Chuo-ku, Sapporo, Hokkaido
060-0061, Japan

Installation and Service of in vitro diagnostic medical devices

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105-8623 Japan

Scope:

Sites included:

Tosoh Techno-System Inc. Hokuriku Service Station
2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan

Scope:

Installation and Service of in vitro diagnostic medical
devices

Tosoh Techno-System Inc. Tohoku Service Station
1-11-1, Hon-cho, Aoba-ku, Sendai, Miyagi 980-0014, Japan

Scope:

Installation and Service of in vitro diagnostic medical
devices

Tosoh Techno-System Inc. Kanagawa Service Station
2743-1, Hayakawa, Ayase, Kanagawa 252-1123, Japan

Scope:

Installation and Service of in vitro diagnostic medical
devices

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Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



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Tokyo
105-8623 Japan

Scope:

Sites included:

Tosoh Techno-System Inc. Nagoya Service Station
1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan

Scope:

Installation and Service of in vitro diagnostic medical devices

Tosoh Techno-System Inc. Osaka Service Station
4-4-9, Kouraihashi, Chuo-ku, Osaka, Osaka 541-0043, Japan

Scope:

Installation and Service of in vitro diagnostic medical devices

Tosoh Techno-System Inc. Hiroshima Service Station
4-6-16, Ootemachi, Nakaku, Hiroshima, Hiroshima 730-0051, Japan

Scope:

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Scope:

Sites included:

Tosoh Techno-System Inc. Kyushu Service Station
1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka 810-0001, Japan

Scope:

Installation and Service of in vitro diagnostic medical devices

Tosoh Hi-Tec, Inc.

1-37, Fukugawa Minami-machi, Shunan, Yamaguchi 746-0042, Japan

Scope:

Design and development and manufacture of in vitro diagnostic medical devices

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105-8623 Japan

Scope:

Sites included:

Tosoh Hi-Tec, Inc. (Tonda)
4560, Kaisei-cho, Shunan, Yamaguchi 746-8501, Japan

Scope:

Design and development and manufacture of in vitro
diagnostic medical devices

Tosoh AIA, Inc.

2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan

Scope:

Design and development and manufacture of in vitro
diagnostic medical devices

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