

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2048822-1

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

Scope: Design and Development, Manufacture, Distribution, Installation and Service of Immunoassay analyzers, Glycohemoglobin analyzers, Molecular testing analyzers, Catecholamine analyzers, High performance liquid chromatography analyzers and Microtitre plate readers.
Design and Development, Manufacture and Distribution of Reagents, Calibrators, Controls, Buffers, Columns, Peripherals, Consumables, Parts and Accessories

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.: 150258732-301

Effective date: 2022-08-31

Expiry date: 2025-08-30

Issue date: 2022-08-30



Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

No.	Facility	Scope
/01	c/o Tosoh Corporation Bioscience Division Planning & Business Development / Sales / Marketing Shiba-koen First Building, 3-8-2, Shiba, Minato-ku, Tokyo 105-8623 Japan	Aspects related to Design and Development and Distribution
/02	c/o Tosoh Corporation Research & Development / Customer Support Center 2743-1, Hayakawa, Ayase, Kanagawa 252-1123 Japan	Aspects related to Design and Development Aspects related to Manufacture of Reagents and Controls. Aspects related to Service
/03	c/o Tosoh Corporation Planning & Business Development / Research & Development 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501 Japan	Aspects related to Design and Development of Reagents, Calibrators, Controls, Buffers, Columns, Consumables and Accessories

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30



Michiaki

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate

**Quality Management System
EN ISO 13485:2016**

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

- | | | |
|-----|--|---------------------------------|
| /04 | c/o Tosoh Corporation
Osaka Branch Bioscience Group
4-4-9, Kouraibashi,
Chuo-ku, Osaka, Osaka
541-0043 Japan | Aspects related to Distribution |
| /05 | c/o Tosoh Corporation
Nagoya Branch Bioscience Group
1-2-7, Sakae,
Naka-ku, Nagoya, Aichi
460-0008 Japan | Aspects related to Distribution |
| /06 | c/o Tosoh Corporation
Sendai Branch
1-11-1, Hon-cho, Aoba-ku,
Sendai, Miyagi
980-0014 Japan | Aspects related to Distribution |
| /07 | c/o Tosoh Corporation
Fukuoka Branch
1-13-2, Tenjin,
Chuo-ku, Fukuoka, Fukuoka
810-0001 Japan | Aspects related to Distribution |

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /08 | c/o Tosoh Techno-System Inc.
Tokyo Service Station
2-5-10, Shiba,
Minato-ku, Tokyo
105-0014 Japan | Aspects related to Installation and Service |
| /09 | c/o Tosoh Techno-System Inc.
Hokkaido Service Station
1-777-12, Shinko-nishi,
Ishikari, Hokkaido
061-3241 Japan | Aspects related to Installation and Service |
| /10 | c/o Tosoh Techno-System Inc.
Hokuriku Service Station
2, Iwasekoshi-machi,
Toyama, Toyama
931-8510 Japan | Aspects related to Installation and Service |
| /11 | c/o Tosoh Techno-System Inc.
Tohoku Service Station
1-11-1, Hon-cho,
Aoba-ku, Sendai, Miyagi
980-0014 Japan | Aspects related to Installation and Service |

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

- | | | |
|-----|---|---|
| /12 | c/o Tosoh Techno-System Inc.
Kanagawa Service Station
2743-1, Hayakawa,
Ayase, Kanagawa
252-1123 Japan | Aspects related to Installation and Service |
| /13 | c/o Tosoh Techno-System Inc.
Nagoya Service Station
1-2-7, Sakae,
Naka-ku, Nagoya, Aichi
460-0008 Japan | Aspects related to Installation and Service |
| /14 | c/o Tosoh Techno-System Inc.
Osaka Service Station
4-4-9, Kouraihashi,
Chuo-ku, Osaka, Osaka
541-0043 Japan | Aspects related to Installation and Service |
| /15 | c/o Tosoh Techno-System Inc.
Hiroshima Service Station
4-6-16, Ootemachi,
Nakaku, Hiroshima, Hiroshima
730-0051 Japan | Aspects related to Installation and Service |

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30



Michiaki Aihara
Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System EN ISO 13485:2016

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

- | | | |
|-----|--|---|
| /16 | c/o Tosoh Techno-System Inc.
Kyushu Service Station
1-13-2, Tenjin,
Chuo-ku, Fukuoka, Fukuoka
810-0001 Japan | Aspects related to Installation and Service |
| /17 | c/o Tosoh Hi-Tec, Inc.
1-37, Fukugawa Minami-machi,
Shunan, Yamaguchi
746-0042 Japan | Aspects related to Design and Development
and Manufacture of Immunoassay analyzers,
Glycohemoglobin analyzers, Molecular
testing analyzers, Catecholamine analyzers,
High performance liquid chromatography
analyzers, Microtitre plate readers,
Peripherals, Consumables, Parts and
Accessories |
| /18 | c/o Tosoh Hi-Tec, Inc. (TRC)
1-37, Fukugawa
Minami-machi, Shunan, Yamaguchi
746-0042 Japan | Aspects related to Design and Development
and Manufacture of Reagents and Controls |
| /19 | c/o Tosoh Hi-Tec, Inc. (Tonda)
4560, Kaisei-cho,
Shunan, Yamaguchi
746-8501 Japan | Aspects related to Design and Development
and Manufacture of Reagents, Calibrators,
Controls, Buffers, Columns, Consumables
and Accessories |

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30



Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02



Michiaki Aihara
Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

Certificate



Quality Management System
EN ISO 13485:2016

Registration No.: SX 2048822-1

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

The scope of certification also covers the following:

/20 c/o Tosoh AIA, Inc.
2, Iwasekoshi-machi,
Toyama, Toyama
931-8510 Japan

Aspects related to Design and Development
and Manufacture of Reagents, Calibrators,
Controls and Buffers


TÜVRheinland

Report No.: 150258732-301
Effective date: 2022-08-31
Expiry date: 2025-08-30
Issue date: 2022-08-30



Michiaki Aihara

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany