

Certificate

Quality Management System EN ISO 13485:2016

Registration No.: SX 2048822-1
Certificate Holder: Tosoh Corporation
2-2-1, Yaesu,
Chuo-ku, Tokyo
104-0028 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.: 150292009-351
Effective date: 2024-04-08
Expiry date: 2025-08-30
Issue date: 2024-04-08
Replaces certificate SX 2048822-1 issued 2023-11-17

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


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

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The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Tosoh Corporation Bioscience Division Planning & Business Development / Sales / Marketing 2-2-1, Yaesu, Chuo-ku, Tokyo 104-0028 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 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
/04	c/o Tosoh Corporation Osaka Branch Bioscience Group 4-4-9, Kouraibashi, Chuo-ku, Osaka, Osaka 541-0043 Japan	Aspects related to Distribution

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- | | | |
|-----|--|---|
| /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 |
| /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 |

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M. Aihara

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- | | | |
|-----|--|---|
| /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 |
| /12 | c/o Tosoh Techno-System Inc.
Kanagawa Service Station /
Technical Center
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 |

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M. Aihara

Michiaki Aihara

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- | | | |
|-----|---|--|
| /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 |
| /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 |

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- | | | |
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| /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 |
| /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 |

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