

Certificate

Standard **ISO 13485:2003, JIS Q 13485:2005**
Certification Registr. No. 81 105 028410

Certification Holder: **Tosoh Corporation**
Bioscience Division
Shiba-Koen First Building, 3-8-2, Shiba, Minato-ku, Tokyo
105-8623, Japan


including the locations according to annex

Scope: Design, Manufacturing, Sales and Services of In Vitro
Diagnostic Medical Devices
Products:
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

Proof has been furnished by means of an audit that the
requirements of ISO 13485:2003, JIS Q 13485:2005 are met.

Validity: This certificate is valid from 2016-08-31 until 2019-02-28.
First certification 2008

2016-08-24


TUV Rheinland Japan Ltd.
3-19-5 Shin-Yokohama, Kohoku-ku
Yokohama 222-0033, Japan

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No.	Location	Scope
81 105 028410/01	Tosoh Corporation Bioscience Division Planning & Business Development / Sales Shiba-koen First Building, 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan	Sales of In Vitro Diagnostic Medical Devices
81 105 028410/02	Research & Development / Customer Support Center 2743-1, Hayakawa, Ayase, Kanagawa 252-1123, Japan	Design, Manufacturing and Services of In Vitro Diagnostic Medical Devices
81 105 028410/03	Separation Media Production / Research & Development 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501, Japan	Design and Manufacturing of In Vitro Diagnostic Medical Devices

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No.	Location	Scope
81 105 028410/04	Osaka Branch Bioscience Group 4-4-9, Kouraihashi, Chuo-ku, Osaka, Osaka 541-0043, Japan	Sales of In Vitro Diagnostic Medical Devices
81 105 028410/05	Nagoya Branch Bioscience Group 1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan	same as above
81 105 028410/06	Sendai Branch 1-11-1, Hon-cho, Aoba-ku, Sendai, Miyagi 980-0014, Japan	same as above
81 105 028410/07	Fukuoka Branch 1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka 810-0001, Japan	same as above

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No.	Location	Scope
81 105 028410/09	Tosoh Techno-System, Inc. Kanagawa Service Station 2743-1, Hayakawa, Ayase, Kanagawa 252-1123, Japan	Services of In Vitro Diagnostic Medical Devices
81 105 028410/11	Tosoh Techno-System, Inc. Tokyo Service Station 2-5-10, Shiba, Minato-ku, Tokyo 105-0014, Japan	same as above
81 105 028410/12	Tosoh Techno-System, Inc. Tohoku Service Station 1-11-1, Hon-cho, Aoba-ku, Sendai, Miyagi 980-0014, Japan	same as above
81 105 028410/13	Tosoh Techno-System, Inc. Nagoya Service Station 1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan	same as above

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No.	Location	Scope
81 105 028410/14	Tosoh Techno-System, Inc. Osaka Service Station 4-4-9, Kouraibashi, Chuo-ku, Osaka, Osaka 541-0043, Japan	Services of In Vitro Diagnostic Medical Devices
81 105 028410/15	Tosoh Techno-System, Inc. Yamaguchi Service Station 1-6-1, Shimizu, Shunan, Yamaguchi 746-0015, Japan	same as above
81 105 028410/16	Tosoh Techno-System, Inc. Kyushu Service Station 1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka 810-0001, Japan	same as above
81 105 028410/17	Tosoh Hi-Tec, Inc. (Tonda) 4560, Kaisei-cho, Shunan, Yamaguchi 746-8501, Japan	Design and Manufacturing of In Vitro Diagnostic Medical Devices

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No.	Location	Scope
81 105 028410/18	Tosoh AIA, Inc. 2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan	Design and Manufacturing of In Vitro Diagnostic Medical Devices
81 105 028410/19	Tosoh Hi-Tec, Inc. 1-37, Fukugawa Minami- machi, Shunan, Yamaguchi 746-0042, Japan	same as above
81 105 028410/20	Tosoh Techno-System, Inc. Hokkaido Service Station Minami 1 Jo Nishi 7-20-1, Chuo-ku, Sapporo, Hokkaido 060-0061, Japan	Services of In Vitro Diagnostic Medical Devices

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