

CERTIFICATE

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

TÜV Rheinland Japan Ltd. Certifies:

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**

An audit was performed, Report No. 028410.
Proof has been furnished that the requirements are fulfilled
according to ISO 13485:2003, JIS Q 13485:2005.
The due date for future audits is 06-11 (mm-dd).

Validity:

This certificate is valid from 2013-08-31 until 2016-08-30.
First certification: 2008
www.tuv.com ID: 9105015173



Yokohama, 2013-08-20

Y. Sumino
TÜV Rheinland Japan Ltd.
3-19-5 Min-Yokohama, Yokohama 222-0033, Japan

Annex to Certificate

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

Location: **TOSOH CORPORATION Bioscience Division / Planning & Business Development / Sales**
Shiba-Koen First Building, 3-8-2 Shiba, Minato-ku, Tokyo 105-8623, Japan

Scope: **Sales of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/01**

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

Scope: **Design, Manufacturing and Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/02**

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

Scope: **Design and Manufacturing of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/03**

Location: **Osaka Branch Bioscience Group**
Yodoyabashi Dai Building, 4-4-9, Kouraihashi, Chuo-ku, Osaka 541-0043, Japan

Scope: **Sales of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/04**

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

Scope: **Sales of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/05**

Location: **Sendai Branch**
Sendai Green Place, 1-11-1, Hon-cho, Aoba-cu, Sendai, Miyagi 980-0014, Japan

Scope: **Sales of In Vitro Diagnostic Medical Devices**
Certification Registry. No. **81 105 028410/06**



Yokohama, 2013-08-20

Y. Sumino
TÜV Rheinland Japan Ltd.
3-19-5 Shin-Yokohama, Yokohama 222-0033, Japan



Annex to Certificate

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

Location: **Fukuoka Branch**
Kogin Building, 1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka
810-0001, Japan

Scope: **Sales of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/07**

Location: **TOSOH TECHNO-SYSTEM INC. Kanagawa Service Station**
2743-1, Hayakawa, Ayase, Kanagawa 252-1123, Japan

Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/09**

Location: **TOSOH TECHNO-SYSTEM INC. Tokyo Service Station**
ND Building, 2-5-10, Shiba, Minato-ku, Tokyo 105-0014,
Japan

Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/11**

Location: **TOSOH TECHNO-SYSTEM INC. Tohoku Service Station**
Sendai Green Place, 1-11-1, Hon-cho, Aoba-ku, Sendai,
Miyagi 980-0014, Japan

Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/12**

Location: **TOSOH TECHNO-SYSTEM INC. Nagoya Service Station**
1-2-7, Sakae, Naka-ku, Nagoya, Aichi 460-0008, Japan

Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/13**

Location: **TOSOH TECHNO-SYSTEM INC. Osaka Service Station**
Yodoyabashi Dai Building, 4-4-9, Kouraibashi, Chuo-ku,
Osaka 541-0043, Japan

Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/14**



Yokohama, 2013-08-20

Y. Sumino
TÜV Rheinland Japan Ltd.
3-19-5 Shimo-Ogino, Yokohama, Yokohama 222-0033, Japan

Annex to Certificate

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

Location: **TOSOH TECHNO-SYSTEM INC. Yamaguchi Service Station**
1-6-1, Shimizu, Shunan, Yamaguchi 746-0015, Japan
Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/15**

Location: **TOSOH TECHNO-SYSTEM INC. Kyushu Service Station**
Kogin Building, 1-13-2, Tenjin, Chuo-ku, Fukuoka, Fukuoka 810-0001, Japan
Scope: **Services of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/16**

Location: **TOSOH HI-TEC, INC. (Tonda)**
4560, Kaisei-cho, Shunan, Yamaguchi 746-8501, Japan
Scope: **Design and Manufacturing of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/17**

Location: **TOSOH AIA, INC.**
2, Iwasekoshi-machi, Toyama, Toyama 931-8510, Japan
Scope: **Design and Manufacturing of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/18**

Location: **TOSOH HI-TEC, INC.**
1-37, Fukugawa, Minami-machi, Shunan, Yamaguchi 746-0042, Japan
Scope: **Design and Manufacturing of In Vitro Diagnostic Medical Devices**
Certification Registr. No. **81 105 028410/19**



Yokohama, 2013-08-20

Y. Sumino
TUV Rheinland Japan Ltd.
3-19-5 Minami-Yokohama, Yokohama 222-0033, Japan