

Certificate

Standard

ISO 13485:2003, JIS Q 13485:2005

Certification Registr. No.

81 105 096362

Certification Holder:

Techno Medica Co., Ltd.

5-5-1, Nakamachidai, Tsuzuki-ku, Yokohama-shi, Kanagawa
224-0041, Japan

including the locations according to annex

Scope:

Development, Design, Manufacturing, Sales, Installation and
Service of In-vitro Diagnostic Medical Devices and Related
Products (reagents and electrodes)¹

Products of In-vitro Diagnostic Medical Devices:1

Blood gas analyzers, Erythrocyte sedimentation rate readers,
Urine chemistry analyzers, Ion Selective analyzers and sensor
card for Blood gas analyzers¹

Manufacturing, Sales of Venous Blood Collection Tubes

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 2016-05-28 until 2019-02-28.
First certification 2010

2016-05-28



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

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Annex to Certificate

Standard **ISO 13485:2003, JIS Q 13485:2005**
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No.	Location	Scope
81 105 096362/01	Headquarters 5-5-1, Nakamachidai, Tsuzuki-ku, Yokohama-shi, Kanagawa 224-0041, Japan	Development, Design, Manufacturing, Sales, Installation and Services of Blood gas analyzers, Erythrocyte sedimentation rate readers, Urine chemistry analyzers, Ion selective analyzers and related Products (reagents and electrodes) Sales, Manufacturing of Venous Blood Collection Tubes
81 105 096362/02	No.2 Laboratory 5-4-9 Nakamachidai, Tsuzuki-ku, Yokohama-shi, Kanagawa 224-0041, Japan	Manufacturing of Sensor Cards for Blood Gas Analyzers and Urine chemistry analyzers
81 105 096362/03	No.3 Laboratory 5-4-6, Nakamachidai, Tsuzuki-ku, Yokohama-shi, Kanagawa 224-0041, Japan	Development and Design of Blood gas analyzers, Urine chemistry analyzers and Ion selective analyzers
81 105 096362/04	No.4 Laboratory 5-4-1, Nakamachidai, Tsuzuki-ku, Yokohama-shi, Kanagawa 224-0041, Japan	Manufacturing of related Products (Reagents and Electrodes) for Blood gas analyzers, Urine chemistry analyzers and Ion selective analyzers

2016-05-28



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