

CERTIFICATE

Standard: **ISO 13485:2003, JIS Q 13485:2005**
Certification Registr. No. **81 105 043429**

TÜV Rheinland Japan Ltd. Certifies:

Certification Holder:

Daiken Medical Co., Ltd.
2-6-2, Ayumino, Izumi-shi, Osaka 594-1157, Japan

including the locations according to annex

Scope:

Design, Development, Manufacturing, and Sales of Medical Devices (Infusion Pump, Syringe Pump, Portable Disposable Infusion Pumps, Water Pasteurization Apparatus, Medical Aspirator, Medical Catheters and Tubes, and Video Rigid Intubation Laryngoscope) Design, Development, and Manufacturing of Medical Devices (Pharynx Cooling Apparatus) Design and Development of Medical Device (Warm Bath Therapy Equipment)

An audit was performed, Report No. 043429.
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 08-20 (mm-dd).

Validity:

This certificate is valid from 2016-01-08 until 2018-11-19.
First certification: 2010
www.tuv.com ID: 9105027080

Yokohama, 2016-01-08

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



**TỔNG GIÁM ĐỐC
YAMAMOTO HAJIME**

Annex to Certificate

Standard: **ISO 13485:2003, JIS Q 13485:2005**
Certification Registr. No. **81 105 043429**

Location: **Headquarters**
3-6-1, Dosho-machi, Cyuo-Ku, Osaka-City, 541-0045, Japan
81 105 043429/01

Certification Registr. No. **Tokyo Branch Office**
Location: 2-4-5 Higashi-Kanda, Chiyoda-ku, Tokyo, 101-0031, Japan
81 105 043429/03

Certification Registr. No. **Sendai Branch Office**
Location: 2-3-7 Uesugi, Aoba-Ku, Sendai-City, 980-0011, Japan
81 105 043429/05

Certification Registr. No. **Nagoya Branch Office**
Location: 1-8-16, Ikeshita-Cho, Chikusa-Ku, Nagoya-City, 464-0067, Japan
81 105 043429/07

Certification Registr. No. **Osaka Branch Office**
Location: 1-6-6, Funakoshi-Cho, Cyuo-Ku, Osaka-City, 540-0036, Japan
81 105 043429/08

Certification Registr. No. **Fukuoka Branch Office**
Location: 3-10-15, Hakata-eki Higashi, Hakata-Ku, Fukuoka-City, 812-0013, Japan
81 105 043429/10

Certification Registr. No. **Sales of Medical Devices (Infusion Pump, Syringe Pump, Portable Disposable Infusion Pumps, Water Pasteurization Apparatus, Medical Aspirator, Medical Catheters and Tubes, and Video Rigid Intubation Laryngoscope)**
Scope:



Yokohama, 2016-01-08

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 043429**

Location: **Yokohama Branch Office**
2-9-40 Kitasaiwai, Nishi-ku, Yokohama-City, 231-0063, Japan
81 105 043429/04

Location: **Sapporo Branch Office**
4-1-19, Kita-10joushi, Kita-ku, Sapporo-City, 001-0010, Japan
81 105 043429/06

Location: **Hiroshima Branch Office**
5-18, Inaricho, Minami-ku, Hiroshima-City, 732-0827, Japan
81 105 043429/09

Location: **Saitama Branch Office**
1-11-1, Sakuragicho, Oomiya-ku, Saitama-City, 330-8540, Japan
81 105 043429/12

Location: **Kanazawa Office**
5-181, Kuratsuki, Kanazawa-City, 920-8203, Japan
81 105 043429/13

Certification Registr. No. **81 105 043429/13**
Scope: **Sales of Medical Devices (Infusion Pump, Syringe Pump, Portable Disposable Infusion Pumps, Medical Aspirator, Medical Catheters and Tubes, and Video Rigid Intubation Laryngoscope)**

Location: **Research & Development Center / Izumi Assembly Center**
2-6-2 Ayumino, Izumi-City, Osaka, 594-1157, Japan
81 105 043429/02

Certification Registr. No. **81 105 043429/02**
Scope: **Design, Development, and Manufacturing of Medical Devices (Infusion Pump, Syringe Pump, Portable Disposable Infusion Pumps, Water pasteurization apparatus, Medical Aspirator, Medical Catheters and Tubes, Video Rigid Intubation Laryngoscope, and Pharynx Cooling Apparatus) Design and Development of Medical Device (Warm Bath Therapy Equipment)**



Yokohama, 2016-01-08

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