# CERTIFICATE

Standard: **ISO 9001:2008, JIS Q 9001:2008**
Certification Registr. No. **09 100 79026**

TÜV Rheinland Cert GmbH certifies:

Certification Holder: **Togo Medikit Co., Ltd.**
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City,
Miyazaki Prefecture 883-0062, Japan

including the locations according to annex

Scope: **Design and Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters, Catheter Introducers, Catheter Introducer Kits and Intravascular Catheter Kits**

An audit was performed, Report No. 79026.
Proof has been furnished that the requirements are fulfilled according to ISO 9001:2008, JIS Q 9001:2008.

The due date for future audits is 04-25 (mm-dd).

Validity: This certificate is valid from 2012-05-01 until 2015-04-30.
First certification: 1998
www.tuv.com ID: 0910579026

DGA-ZM-58-95-00

Yokohama, 2012-04-26

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

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# Annex to Certificate

Standard: **ISO 9001:2008, JIS Q 9001:2008**
Certification Registr. No. **09 100 79026**

| | |
|---|---|
| Location: | **Togo Medikit Co., Ltd.**<br>**Hyuga Factory**<br>17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City,<br>Miyazaki Prefecture 883-0062, Japan |
| Scope: | **Design and Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters, Catheter Introducers, Catheter Introducer Kits and Intravascular Catheter Kits** |
| Certification Registr. No. | **09 100 79026/01** |
| Location: | **Togo Medikit Co., Ltd.**<br>**Medikit Hyuga Second Factory**<br>435-3, Hei, Aza Kakinokida, Togo-cho, Hyuga City,<br>Miyazaki Prefecture 883-0102, Japan |
| Scope: | **Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters and Catheter Introducers and Intravascular Catheter Kits** |
| Certification Registr. No. | **09 100 79026/02** |
| Location: | **Togo Medikit Co., Ltd.**<br>**Sakura Factory**<br>1-6-1, Osaku, Sakura City, Chiba Prefecture 285-0802, Japan |
| Scope: | **Manufacturing of Catheter Introducer Kits** |
| Certification Registr. No. | **09 100 79026/03** |
| Location: | **Medikit Vietnam Co., Ltd.**<br>**Vietnam Factory**<br>Nomura-Haiphong I Z, An Duong District, Haiphong-city,<br>Vietnam |
| Scope: | **Manufacturing of Dialysis Cannulae, Indwelling Cannulae and Catheter Introducers and Intravascular Catheter Kits** |
| Certification Registr. No. | **09 100 79026/04** |

DGA-ZM-58-95-00

Yokohama, 2012-04-26

TÜV Rheinland Cert GmbH
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# Annex to Certificate

Certification Registr. No. **09 100 79026**
Standard: **ISO 9001:2000, JIS Q 9001:2000**

| | |
|---|---|
| Location: | **Medikit Vietnam Co., Ltd.**<br>**Vietnam Factory**<br>Standard Factory B-3 & D-3, Nomura-Haiphong I Z, An Duong District, Haiphong-city, Vietnam |
| Scope: | Manufacturing of Dialysis Cannulae, Indwelling Cannulae and Catheter Introducers |
| Certification Registr. No. | 09 100 79026/4 |

Yokohama, 2009-04-28

TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

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TGA-ZM-58-95-00

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# CERTIFICATE

Standard: **ISO 13485:2003, JIS Q 13485:2005**
Certification Registr. No. **81 105 79026**

TÜV Rheinland Japan Ltd. Certifies:

Certification Holder: **Togo Medikit Co., Ltd.**
17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City,
Miyazaki Prefecture 883-0062, Japan

including the locations according to annex

Scope: **Design and Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters, Catheter Introducers and Catheter Introducer Kits and Intravascular Catheter Kits**

An audit was performed, Report No. 79026.
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 04-25 (mm-dd).

Validity: This certificate is valid from 2012-05-01 until 2015-04-30.

First certification: 2009
www.tuv.com ID: 0910579026

Yokohama, 2012-04-26

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

www.tuv.com

JAB CM046

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# Annex to Certificate

Standard: **ISO 13485:2003, JIS Q 13485:2005**
Certification Registr. No. **81 105 79026**

| | |
|---|---|
| Location: | **Togo Medikit Co., Ltd.**<br>**Hyuga Factory**<br>17148-6, Aza Kamekawa, Oaza Hichiya, Hyuga City, Miyazaki Prefecture 883-0062, Japan |
| Scope: | **Design and Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters, Catheter Introducers and Catheter Introducer Kits and Intravascular Catheter Kits** |
| Certification Registr. No. | **81 105 79026 /01** |
| Location: | **Togo Medikit Co., Ltd. Medikit**<br>**Hyuga Second Factory**<br>435-3, Hei, Aza Kakinokida, Togo-cho, Hyuga City, Miyazaki Prefecture 883-0102, Japan |
| Scope: | **Manufacturing of Dialysis Cannulae, Indwelling Cannulae, Catheters and Catheter Introducers and Intravascular Catheter Kits** |
| Certification Registr. No. | **81 105 79026 /02** |
| Location: | **Togo Medikit Co., Ltd.**<br>**Sakura Factory**<br>1-6-1, Osaku, Sakura City, Chiba Prefecture 285-0802, Japan |
| Scope: | **Manufacturing of Catheter Introducer Kits** |
| Certification Registr. No. | **81 105 79026 /03** |
| Location: | **Medikit Vietnam Co., Ltd.**<br>**Vietnam Factory**<br>Nomura-Haiphong IZ, An Duong District, Haiphong-city, Vietnam |
| Scope: | **Manufacturing of Dialysis Cannulae, Indwelling Cannulae and Catheter Introducers and Intravascular Catheter Kits** |
| Certification Registr. No. | **81 105 79026 /04** |

Yokohama, 2012-04-26

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

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JAB CM046

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# Annex to Certificate

Certification Registr. No. **81 105 79026**
Standard: **ISO 13485:2003, JIS Q 13485:2005**

| | |
|---|---|
| Location: | **Medikit Vietnam Co., Ltd. Vietnam Factory**<br>Standard Factory B-3 & D-3, Nomura-Haiphong IZ, An Duong District, Haiphong-city, Vietnam |
| Scope: | Manufacturing of Dialysis Cannulae, Indwelling Cannulae and Catheter Introducers |
| Certification Registr. No. | 81 105 79026 /4 |

Yokohama, 2009-04-28

TÜV Rheinland Japan Ltd.
Certification of Management Systems
3-19-5 Shin-Yokohama, Yokohama 222-0033, Japan

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# APPROVAL

## EC Directive 93/42/EEC Annex II, Article 3
## Full Quality Assurance System
## Medical Devices

**Registration No.:** HD 60027890 0001

**Report No.:** 12018112 001

**Manufacturer:**
Togo Medikit Co., Ltd.
17148-6, Aza Kamekawa,
Oaza Hichiya Hyuga City
MIYAZAKI PREFECTURE 883-0062
JAPAN

**Scope:**
Design/Development and Manufacture of Dialysis Cannulae, Indwelling Cannulae and Catheter Introducers

(see attachment for additional sites included)

Replaces Approval, Registration No.: HD 60008967 0001

**Date of Expiry:** 25.07.2014

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Date 18.02.2010

Dipl.-Ing. U. Frenkert

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE

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Doc. 1/1, Rev .0

# TÜV Rheinland
# LGA Products GmbH
# Tillystraße 2, 90431 Nürnberg

**Attachment to**
**Registration No.:** HD 60027890 0001
**Report No.:** 12018112 001

**Manufacturer:**

Togo Medikit Co., Ltd.
17148-6, Aza Kamekawa,
Oaza Hichiya Hyuga City
MIYAZAKI PREFECTURE 883-0062
JAPAN

**Scope:**

Production and ethylene oxide sterilization facility:

Togo Medikit Co., Ltd. Hyuga Factory
17148-6, Aza Kamekawa, Oaza Hichiya Hyuga City,
Miyazaki Prefecture 883-0062, Japan

Production facility:

Togo Medikit Co., Ltd. Hyuga Second Factory
435-3, Hei, Aza Kakinokida, Togo-cho, Hyuga City
Miyazaki Prefecture 883-0102, Japan

**Certification Body**

**Date** 18.02.2010

Dipl.-Ing. U. Frenkert