

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60114706 0001

Report No.: 12022685 006

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

Products: Dialysis Cannulae, Indwelling Cannulae, Catheter
Introducers, Intravascular Catheter Kits and
Angiographic Catheters
(see attachments for sites included)

Replaces Approval, Registration No.: HD 60094868 0001

Expiry Date: 2019-06-30

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2016-11-24

Date: 2016-11-24



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev .0

**Attachment to
Certificate**

Registration No.: HD 60114706 0001
Report No.: 12022685 006

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

Products and Sites included:

Manufacturing and Ethylene Oxide Sterilization site:

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

Manufacturing site:

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

- Dialysis Cannulae
- Indwelling Cannulae
- Catheter Introducers
- Intravascular Catheter Kits
- Angiographic Catheters

Date: 2016-11-24



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev .0

**Attachment to
Certificate**

Registration No.: HD 60114706 0001
Report No.: 12022685 006

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

Products and Sites included:

Manufacturing site:

Medikit Vietnam Co., Ltd. Vietnam Factory
Nomura-Haiphong IZ, An Duong District, Haiphong-city,
Vietnam

- Dialysis Cannulae
- Indwelling Cannulae
- Intravascular Catheter Kits

Manufacturing site:

Togo Medikit Co., Ltd. Togo Factory
1114, Tei, Yamage, Togo-cho, Hyuga City, Miyazaki Prefecture
883-0103, Japan

- Parts of Dialysis Cannulae and Indwelling Cannulae
(Metallic Needles)

Date: 2016-11-24



Notified Body


M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev .0

**Attachment to
Certificate**

Registration No.: HD 60114706 0001
Report No.: 12022685 006

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

Products and Sites included:

Ethylene Oxide Sterilization sites:

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

Medikit Vietnam Co., Ltd. Vietnam Factory
Nomura-Haiphong IZ, An Duong District, Haiphong-city,
Vietnam

- Indwelling Cannulae

Date: 2016-11-24



Notified Body


M.Sc. M. Aihara