ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 09 77591 012

Manufacturer:
Hitec Medical Co., Ltd.
No. 1328, Hengnan RD, Minhang District
201114 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Urethral Catheters, Tracheostomy Tube, Silicone Foley Catheter, Foley Catheter with Temperature Sensor

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH16709EXT01

Valid from: 2016-11-03
Valid until: 2021-11-02

Date, 2016-10-10

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 09 77591 012

Facility(ies):

Hitec Medical Co., Ltd.
No. 1328, Hengnan RD, Minhang District, 201114
Shanghai, PEOPLE'S REPUBLIC OF CHINA

FIRMA DE PRODUCERE ŞI COMERŢ "SOGNO" S.R.L. REPUBLICA MOLDOVA, mun. CHIŞINĂU IDNO 1004600013854 Sogno® S.R.L.

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TÜV SÜD
Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 08 77591 018

Manufacturer: **Hitec Medical Co., Ltd.**
No. 703, Hengnan RD 1328
Minhang District
201114 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative: **Shanghai International Holding Corp. GmbH (Europe)**
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies): **Urethral Catheters, Tracheostomy Tube, Silicone Foley Catheter, Foley Catheter with Temperature Sensor**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1770907

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Date, 2017-10-23

Stefan Preiß

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