ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 11 11 75606 004

Manufacturer:

Purecath Medical (Shanghai) Co., Ltd.
2A, 6 Building, No. 328, Jinglian Road
201108 Shanghai
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

Sterile Urethral Catheter for Single Use, Suction Catheter for Use in the Respiratory Tract, Nasal Oxygen Cannula, Blood Pressure Transducer Set, Tracheal Tubes, Tracheostomy Tubes

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.: SH1164202

Valid from: 2012-02-24
Valid until: 2015-12-15

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Date, 2012-02-28

Hans-Heiner Junker

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

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Facility(ies):

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2A, 6 Building, No. 328, Jinglian Road, 201108
Shanghai, PEOPLE'S REPUBLIC OF CHINA

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