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

Product Service

CERTIFICATE

No. Q1N 12 04 15198 024

Holder of Certificate: **Bionic Medizintechnik GmbH**
Max-Planck-Straße 21
61381 Friedrichsdorf
GERMANY

Facility(ies):
Bionic Medizintechnik GmbH
Max-Planck-Straße 21, 61381 Friedrichsdorf, GERMANY

Certification Mark:

Scope of Certificate: **Development, Production and Distribution of needles and catheters for vascular access, sterile single use devices for infusion and transfusion therapy, connection and disconnection sets, therapy chairs and furniture**

Applied Standard(s):
EN ISO 13485: 2003 / AC:2009
Medizinprodukte - Qualitätsmanagementsysteme - Anforderungen für regulatorische Zwecke
Medical Devices - Quality Management Systems - Requirements for regulatory purposes

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713001135

Valid from: 2012-06-12
Valid until: 2015-05-31

Date, 2012-06-13

Hans-Heiner Junker

469962

TÜV SÜD Product Service GmbH
Zertifizierstelle
Ridlerstraße 65 · 80339 München
Germany

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-999.98.12-46

TÜV®

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 12 04 15198 023

Manufacturer: **Bionic Medizintechnik GmbH**
Max-Planck-Straße 21
61381 Friedrichsdorf
GERMANY

Product Category(ies): **Fistula Needles**
Dialysis Catheters
Connection and Disconnection Sets
(Products see attachment)

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.: 713000060

Valid from: 2012-05-29
Valid until: 2017-05-28

Date, 2012-04-18

Hans-Heiner Junker

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

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 12 04 15198 023

Facility(ies):

Bionic Medizintechnik GmbH
Max-Planck-Straße 21, 61381 Friedrichsdorf, GERMANY

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

Product Service

Attachment to Certificate no G1 12 04 15198 023
dated 2012-04-18

Products:

Fistula needles, fixed wing

Fistula needles, rotating hub

Fistula needles, „Single Needle"

Fistula needles, „Button Hole"

Safety fistula needles

Dialysis Connection and Disconnection Sets

Dialysis catheters, single and multi lumen

Dialysis catheter sets

Dialysis catheter, accessories

DEMERS catheter, implantable

Munich, CRT2, 2012-04-18

Hans-Heiner Junker

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany