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

Product Service

EC Certificate

Production Quality Assurance System

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

No. G2 16 03 95187 001

Manufacturer:
Statcorp Medical
35301 SE Center Street
Snoqualmie WA 98065
USA

EC-Representative:
MediMark Europe Sarl
11, Rue Emile Zola - BP 2332
38033 Grenoble Cedex 2
FRANCE

Product Category(ies):
Pressure Cuffs for the Infusion of Fluids

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

Report No.: 72114275

Valid from: 2016-12-13
Valid until: 2021-12-12

Date, 2016-12-13

Stefan Preiß

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

TÜV®

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Facility(ies):

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

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