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 I in sterile conditions, sterilised systems or procedure packs)

No. G2S 18 02 15692 045

Manufacturer:

P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53
50996 Köln
GERMANY

Facility(ies):

P. J. Dahlhausen & Co. GmbH
Emil-Hoffmann-Str. 53, 50996 Köln, GERMANY

Product Category(ies):

Sterile medical disposables (class I) for anaesthesia, surgery, intensive care and ward equipment
for further details see attachment

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713125906_2

Valid from: 2018-06-07
Valid until: 2023-05-19

Date, 2018-06-07

Stefan Preiß

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

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Product Service

Attachment to Certificate no G2S 18 02 15692 045
dated 2018-06-07

Medical Devices Class I

Products / Product Groups:

Sterile Guedel airways
Sterile video camera drapes
Sterile examination gloves
Sterile catheter kits
Sterile suture removal kits
Sterile urine drainage bags
Sterile infusion accessories
Sterile Remover for skin stapler
Sterile cover for surgical light handle

Munich, CRT, 2018-06-07

Stefan Preiß

HAMBURG
PRODUCT SERVICE

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

TÜV®