ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ 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 16 10 47326 008

Manufacturer:

IVF HARTMANN AG
Victor-von-Bruns-Strasse 28
8212 Neuhausen am Rheinfall
SWITZERLAND

Facility(ies):

IVF HARTMANN AG
Victor-von-Bruns-Strasse 28, 8212 Neuhausen am Rheinfall,
SWITZERLAND

Product Category(ies):

Compresses, surgical drapes, primarily wound dressings, hydroactive dressings, sterile medical systems for care, wound care, therapy, analysis, catheterisation and anaesthesia

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.: 713093073

Valid from: 2017-01-17
Valid until: 2022-01-16

Date, 2016-11-16

Stefan Preiß

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

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