ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

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 062831 0008 Rev. 00

Manufacturer

Fomed Industries Inc
20 Han Sha Road
Hou Hu District
433115 Qian Jiang City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

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

Product Category(ies):

Sterile gauze swabs (without X-Ray), Sterile gauze ball (without X-Ray), Sterile cotton filled sponges, Sterile tracheotomy sponges, Sterile drain gauze swabs, Sterile surgical towels, Sterile non-woven swabs, Sterile drain non-woven swabs, Sterile non-woven ball, Sterile dental cotton roll, Sterile cotton ball, Sterile cotton tipped applicators, Sterile conforming bandages, Sterile gauze bandages, Sterile fluff gauze roll, Sterile absorbent dressing pads (ABD pads), Sterile dressing sets, Sterile tongue depressors

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.: SH1817101

Valid from: 2019-05-07
Valid until: 2024-05-06

Date, 2019-05-07

Stefan Preiß

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Facility(ies):

Fomed Industries Inc
20 Han Sha Road, Hou Hu District, 433115 Qian Jiang City, Hubei Province, PEOPLE'S REPUBLIC OF CHINA

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Digitally signed by Nebora Vera
Date: 2022.06.30 10:49:45 EEST
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