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 IIa, IIb or III)

No. G2 097364 0008 Rev. 02

Manufacturer:

Kingstar Medical (Xianning) Co., LTD
No. 79 Yong'andong Road
Xian'an District
437100 Xianning City, Hubei Province
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

Sterile/Nonsterile X-Ray Detectable Gauze Balls,
Sterile/Nonsterile X-Ray Detectable Gauze Sponges,
Sterile/Nonsterile X-Ray Detectable Lap Sponges,
Sterile/Nonsterile X-Ray Detectable Gauze Rolls,
Sterile/Nonsterile X-Ray Detectable Gauze-Nonwoven Lap Sponges,
Sterile/Nonsterile X-Ray Detectable Non-woven Sponges,
Sterile/Nonsterile X-Ray Detectable Non-woven Balls,
Medical Dressing Kits

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G2 097364 0008 Rev. 02

Report No.: SH2093902

Valid from: 2020-12-01
Valid until: 2024-05-26

Date, 2020-12-01

Christoph Dicks
Head of Certification/Notified Body

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

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