ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ 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 17 09 99455 002

Manufacturer:
Jiangsu Kezhi Medical Technology Co.,Ltd
Laozhangji Industrial Park
Huaiyin District
223300 Huaian
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:
Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):
Disposable Nasal Oxygen Cannula,
Disposable Suction Connecting Tube,
Disposable Oxygen Mask,
Disposable Infusion Device with Needle

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.: SH17120101

Valid from: 2018-02-09
Valid until: 2023-02-08

04052767965449

Date, 2018-02-09

Stefan Preiß

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

Digitally signed by Iarovoi Petru
Date: 2021.12.30 16:41:11 EET
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Facility(ies):

Jiangsu Kezhi Medical Technology Co.,Ltd
Laozhangji Industrial Park, Huaiyin District, 223300
Huaian, PEOPLE'S REPUBLIC OF CHINA

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

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