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 18 01 96468 004

Manufacturer:

Jiangsu Shuangsheng Medical Appliance Co., Ltd.
Dandong Industrial Park, Danyang City
(No.12 Lingkou 122 Highway Industrial Zone)
212353 Danyang
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Prolinx GmbH
Brehmstr. 56
40239 Duesseldorf
GERMANY

Product Category(ies):

Oxygen Concentrator, Portable Phlegm Suction Unit, Nebulizer

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.: SH18109202

Valid from: 2018-05-29
Valid until: 2022-06-27

04052768655332

Date, 2018-05-29

Stefan Preiß

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

TÜV®