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 063599 0022 Rev. 02**

**Manufacturer**

**Beijing Demax Medical Technology Co.,Ltd**
A13-7, Jingshengnansi Street, Tongzhou District
101102 Beijing
PEOPLE'S REPUBLIC OF CHINA

**Product Category(ies):**

**Balloon In-deflation Device.**

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. 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:G2S 063599 0022 Rev. 02

**Report No.:** BJ20092002

**Valid from:** 2020-08-28
**Valid until:** 2024-05-26

**Date,** 2020-08-28

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Ostapciuc Alexandr
Date: 2023.10.11 10:40:40 EEST
Reason: MoldSign Signature
Location: Moldova


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

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