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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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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 102375 0002 Rev. 00

Manufacturer	**Henan Medical Technology Co., LTD.** Room 816, Building B No. 3, Xiangsheng Street Zhengdong New District 450000 Zhengzhou City, Henan Province PEOPLE'S REPUBLIC OF CHINA
EC-Representative:	Luxus Lebenswelt GmbH Kochstr. 1, 47877 Willich, GERMANY
Product Category(ies):	**Surgical Pack,** **Surgical Drape,** **Surgical Gown**

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.: SH1891501

Valid from: 2019-06-11
Valid until: 2024-05-26

Date, 2019-06-11

Stefan Preiß
Head of Certification/Notified Body

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

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Facility(ies):

Henan Medical Technology Co., LTD.
Room 816, Building B, No. 3, Xiangsheng Street,
Zhengdong New District, 450000 Zhengzhou City,
Henan Province, PEOPLE'S REPUBLIC OF CHINA

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