



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 005447 0002 Rev. 00

Manufacturer

**Anhui MedPurest
Medical Technology Co.,Ltd**

Jia Bao Industrial Park
246000 Anqing, Anhui Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Anhui MedPurest Medical Technology Co.,Ltd
Jia Bao Industrial Park, 246000 Anqing, Anhui Province,
PEOPLE'S REPUBLIC OF CHINA

Product Category(ies):

**Sterile Surgical Gowns,
Sterile Surgical Drapes,
Sterile Surgical Packs**

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.:

SH18131201

Valid from:

2018-10-30

Valid until:

2023-10-29

Date,

2018-10-30

Stefan Preiß

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

**ANHUI MEDPUREST MEDICAL
TECHNOLOGY CO.,LTD**
Sanyi Road, Daqiao Economic and Technological
Development Zone, Anqing ,
Anhui Province, China

has established and applies a quality management system for medical devices
for the following scope:

**Manufacture and Distribution of Surgical Drapes, Surgical
Packs, Surgical Gowns, Nonwoven Bedsheets, Nonwoven
Pillowcases, Nonwoven Masks**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-05-15
Certificate Registration No.: SX 60129456 0001
An audit was performed. Report No.: 15055315 008
This Certificate is valid until: 2021-01-18

Certification Body



Date 2018-05-15



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