Declaration of Conformity

CE 符合性聲明

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According to the Medical Device Directive 93/42/EEC

按照医疗器械指令 93/42/EEC

Manufacturer: Anhui MedPurest Medical Technology Co.,Ltd

安徽迈德普斯医疗科技有限公司

Address: Jia Bao Industrial Park, 246000，Anqing, Anhui Province , PEOPLE'S REPLUBLIC OF CHINA

地址： 安徽省安庆市加宝工业园

Authorized Representative: Name: Prolinx GmbH

Address: Brehmstraße 56,40239,Düsseldorf,Germany

授权代表

Certificate number: G2S 005447 0002 Rev.00 (Annex V)

Medical Device: 医疗器械

Product Name: MedPurest Brand

SURGICAL GOWN

Model name: MDSG-1052

Digitally signed by Guțan Ghenadie
Date: 2022.01.19 09:12:49 EET
Reason: MoldSign Signature
Location: Moldova

MDD-Classification:	Class I
MDD-分类	级别 1

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European Medical Device Directive 93/42/EEC(MDD).Applying ISO13485:2003 Medical Devices - Quality Management Systems and the production is in accordance with EN868, ISO11607&EN13795, The Items above are all sterilization before shipping.

兹签字声明以上所列医疗器械符合欧洲医疗器械指令 93/42/EEC(MDD)附件 1 列明的必要要求。适用 ISO13485:2003 医疗器械-质量管理体系，并依照欧洲标准 EN868 国际标准 ISO11607 和 EN13795。

This declaration of conformity is based on the European Medical Device Directive 93/42/EEC, Annex<V> and is supported by The Certification Body Of TUV PRODUCT SERVICE GMBH, with reference to articles 1 and 3 of the MDD.

参照 MDD 第 1 款和第 3 款，这份符合性声明是基于欧洲医疗器械指令 93/42/EEC 附件(V)设立，并受南德意志 TUV 认证方的支持。

General Manager:

总经理

ANQING Jan.10th ,2020

(Place and date of issue)

龙亮亮

（Name and signature）