

Excellent Medical CE Technical Documentation	Document No.: EXCE-04-03 Declaration of Conformity	Rev.#: Effective Date:	C 2023-05-17
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EC DECLARATION OF CONFORMITY

Manufacturer: Excellent Medical Technology Group Co., Ltd.

SRN# CN-MF-000022462

Address: Room2301, Decheng Jiayuan Plaza, No.1539, Xiangcheng Rd., Xiangcheng, Suzhou, Jiangsu Province, 215131 P.R. China

Authorized Representative Shanghai International Holding Corp.GmbH (Europe)
Eiffestrasse 80, 20537 Hamburg, Germany

Authorized Rep. SRN# DE-AR-000000001

Product name Disposable Surgical Gowns, Surgical Gowns, Surgical Isolation Gowns

Model code Size/Model.S,M,L, XL, XXL, XXXL for all types

Product trade name: Surgical Gowns, Surgical Isolation Gowns

Basic UDI-DI 697282318STGOWNSD9

EMDN Code T020402

Intended use: It is used to isolate patients and equipment in operating rooms during various medical operations.

Classification : Is , Annex VIII Chapter III,Rule I

Conformity Assessment Route: Medical Device Regulations 2017/745, Annex XI Part A

We herewith declare that the above mentioned products meet the provisions of the following EU Regulations. All supporting documentations are retained under the premises of the manufacturer. The EU declaration of conformity is issued under our sole responsibility.

REGULATIONS

General applicable Regulations:

Regulation (EU) 2017/745 of European Parliament and of the Council of 5 April 2017 on medical device,amending Directive 2001/83/EC,Regulation(EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Notified Body : TUV SUD Product Service GmbH

Quality Management System : ISO 13485: 2016

MDR EC Certificate No : G21 002715 0002 Rev.00

Valid to : 2029-05-14

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Room 2301, Decheng Jiayuan Plaza, No.1539 Xiangcheng Road, Xiangcheng District,
215131 Suzhou, Jiangsu, P.R.CHINA

Signature of issued person:



Suzhou, 2024/5/17

QARA

Place, date

Name and function

Annex I

Model code	Basic UDI-DI(inner bags)	Basic UDI-DI(inner boxes)	Basic UDI-DI (outer carton)
SGS35-1	6972823180013	6972823180020	6972823180037
SGS35-2	6972823180044	6972823180051	6972823180068
SGS35-3	6972823180075	6972823180082	6972823180099
SGS35-4	6972823180105	6972823180112	6972823180129
SGS35-5	6972823180136	6972823180143	6972823180150
SGR35-1	6972823180167	6972823180174	6972823180181
SGR35-2	6972823180198	6972823180204	6972823180211
SGR35-3	6972823180228	6972823180235	6972823180242
SGR35-4	6972823180259	6972823180266	6972823180273
SGR35-5	6972823180280	6972823180297	6972823180303
SGS43-1	6972823180310		6972823180327
SGS43-2	6972823180334		6972823180341
SGS43-3	6972823180358		6972823180365
SGS43-4	6972823180372		6972823180389
SGS43-5	6972823180396		6972823180402
SGR43-1	6972823180419		6972823180426
SGR43-2	6972823180433		6972823180440
SGR43-3	6972823180457		6972823180464
SGR43-4	6972823180471		6972823180488
SGR43-5	6972823180495		6972823180501
SGS35-1E	26972823186200		06972823186206
SGS35-2E	26972823186217		06972823186213
SGS35-3E	26972823186224		06972823186220
SGS35-4E	26972823186248		06972823186244
SGS35-5E	26972823186255		06972823186251
SGR35-1E	26972823186262		06972823186268
SGR35-2E	26972823186279		06972823186275
SGR35-3E	26972823186286		06972823186282
SGR35-4E	26972823186293		06972823186299
SGR35-5E	26972823186309		06972823186305