

Excellent Medical CE Technical Documentation	Document No.: CE-03-03 Declaration of Conformity	Rev.#: Effective Date:	C 2024-05-17
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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 Drapes
Model code	Size/Model.45cm*55cm~230cm*320cm
Product trade name:	Disposable Surgical Drapes, Surgical Drapes, Fluid Collection Pouch to drapes
Basic UDI-DI	697282318STDRAPEsqv
EMDN Code	T020102
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, May 17, 2024

\_\_\_\_\_  
Place, date

\_\_\_\_\_  
Name and function

QARA

## Annex II

Model code	Basic UDI-DI(inner bags)	Basic UDI-DI(inner boxes)	Basic UDI-DI (outer carton)
REF	EAN code for inner bags	EAN code for boxes	EAN code for outer carton
PC-1	06972823183601		06972823183618
PC-2	06972823183878		06972823183885
PC-3	06972823180518		06972823180525
ETEC75	06972823182888		06972823182895
ETEC90	06972823182901		06972823182918
ETEC140	06972823182925		06972823182932
ETEC150			
ETECV9070			
ECARM-SD-1	06972823184264	06972823184271	06972823184288
MTC-80140	36972823186573	26972823186576	06972823186572
MTC-80140+	36972823186580	26972823186583	06972823186589
E1050	06972823182444		06972823182451
EFP-SD-1	06972823181249		06972823181256
E22530	06972823182574		06972823182581
E22535	06972823181225		06972823181232
EL75120	06972823181034	06972823181041	06972823181058
AC-1	06972823182468		06972823182475
AC-2	06972823180631		06972823180648
E3845C	06972823180921		06972823180938
E4575C	06972823182611		06972823182628
E5050C	06972823182703		06972823182710
E5060C	06972823182727		06972823182734
E7590C	36972823186597	26972823186590	06972823186596
E100150C	36972823186603	26972823186606	06972823186602
E150140C			
E150190C	06972823180679	06972823184837	06972823180686
E150190C+	06972823184899	06972823184905	06972823184912
EA4575C	06972823183977		06972823183984
EA5060C	36972823186610	26972823186613	06972823186619
EA6075C			
EA7580C	06972823180945		06972823180952
EA7590C	36972823186627	26972823186620	06972823186626
EA100125C	06972823182765	06972823182772	06972823182789
EA120150C	06972823183649		06972823183656
EA150180C	06972823182635	06972823184257	06972823182642
EA150180C-2	06972823182796	06972823182802	06972823182819
EA200280C+			
EAV75100C	06972823184974		06972823184981
EV5075C	06972823184042		06972823184059
EV7590C	06972823180730		06972823180747
EV7590C+	06972823183663	26972823183667	06972823183670
EV100100C+	06972823184943	06972823184950	06972823184967
EV100150C+	36972823186191	26972823186194	06972823186190
EV175175C	06972823182826	06972823184936	06972823182833

EV175175C+			
EV175175A	06972823183991		06972823184004
EV180150C	06972823182840		06972823182857
EV250180C	06972823184417	06972823184424	06972823184431
EV240150A	06972823182864		06972823182871
EV240150C			
EV240150C+	06972823184554	06972823184561	06972823184578
E100150A	06972823184875		06972823184882
OPHT-SD-2	06972823181263		06972823181270
OPHT-SD-3-2	06972823183892		06972823183908
OPHT-SD-3-3	06972823181287		06972823181294
OPHT-SD-4	06972823184080	06972823184097	06972823184103
EEX-SD-1C	06972823182659	26972823182653	06972823182666
EEX-SD-2C	06972823184189		06972823184196
EU-SD-3C	06972823180983	06972823180990	06972823181003
EU-SD-4C	06972823181300	06972823181317	06972823181324
EU-SD-5C	06972823183687	06972823183694	06972823183700
ELAP-SD-4A	06972823184295	06972823184301	06972823184318
EDEL	06972823180969		06972823180976
DEL-2	06972823182512		06972823182529
DEL-3	06972823180556		06972823180563
DEL-5	06972823184233		06972823184240
OPHT-4	06972823181331	06972823181348	06972823181355
OPHT-5	06972823184011	06972823184028	06972823184035
OPHT-6	06972823182673	06972823182680	06972823182697
EUNIVS-2C	06972823180754	06972823180761	06972823180778
EUNIVS-2C+	06972823180785	06972823180792	06972823180808
EUNIVS-2A+	06972823182482	06972823182499	06972823182505
ART-1	06972823180570	06972823180587	06972823180594
ART-1C			
ART-2	06972823180600	06972823180617	06972823180624
ART-2C			
EHIPS-1A	06972823182970	06972823182987	06972823182994
EDENT-1C	06972823182949	06972823182956	06972823182963
ETURS-1	06972823184110	06972823184127	06972823184134
ETURS-2			
ETURS-3			
EUS-1C+	06972823184202	06972823184219	06972823184226
EANGS-1	06972823183915	06972823183939	06972823183922
EANGS-2	06972823184844	06972823184851	06972823184868
EANG-SD-1	06972823182536	06972823182543	06972823182550
EANG-SD-1C			
BED-1	06972823180815		06972823180839
OPHT-SD-1-2	06972823184325		06972823184349
EGYNS-2	36972823186085	26972823186088	06972823186084
EANGS-3A	36972823186061	26972823186064	06972823186060
E100150C+	06972823184998	06972823185001	06972823185018
EV300175C	06972823185100		06972823185117
ECSECS-2	06972823185803	06972823185810	06972823185827
EDP-SD-2			
E100100C			
E120140C			

EV5050C			
EV5050A			
EV5075A			
EV5060C			
OPHT-SD-1			
LOPT-1			
LOPT-2			
LOPT-3			
ART-3C+G			
EHIPS-2A+G			