



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-IG-14.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

SHANGHAI JOY CROWN INDUSTRY CO., LTD.
Rm.1105, No.55-56 Lane 21 Pu San Road, Pu
Dong New Area, 200125 Shanghai, P.R.China.
SRN: CN-MF-000009005

Product Information

Name: ISOLATION GOWN
Model: JC03014
GMDN: 35492
Basic UDI-DI: 697457898JC03014PS
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products with CE mark are fully compliance with General Safety Performance Requirement of the Medical Device Regulation (MDR) 2017/745. All supporting documents are retained at the premise of manufacturer.

上海仪冠实业有限公司
SHANGHAI JOY CROWN INDUSTRY CO., LTD.
Yu Yao Gen

General Manager

Date: 12/08/2021

Place: Shanghai/China

上海仪冠实业有限公司
SHANGHAI JOY CROWN INDUSTRY CO., LTD
TEST REPORT

Product Name:	ISOLATION GOWN	SC NO.	JC-23-0015
Batch No.	20230215	Item	Complete Test
Standard	B.P.98	Report Date	2023/2/20
Size:	110CM X 145CM	110 x 145 cm	
Weight	18g/m2 +/-2g/m2	18g/m2	
Colour	Blue	Good	
Stiches	6-7 stiches per 3 cm	Good	
Package	10 pcs/ bag with label	Good	
Test Report Data	The Standard of Sanitation:	≤100cfu/g	
	The Result Data:	≤10cfu/g	
Conclusion: In subject to B.P. 98 Standard			

Inspector: Zhang Yunyun

Review: Pan Li

上海仪冠实业有限公司
SHANGHAI JOY CROWN INDUSTRY CO., LTD.