EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Carestone Medical & Protective Products Co., Ltd. 1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China
SRN:	CN-MF-000027756
European Representative	Luxus Lebenswelt GmbH Kochstr .1, 47877, Wilich, Germany Tel :0049-1715605732 E-mail: info.m@luxuslw.de
SRN:	DE-AR-000005110
Trade Name:	Isolation Gown
Product nName:	Isolation Gown
Specification:	S-110*110cm, M-110x120cm, L-115x137cm, XL-120x140cm, XXL-130x150cm, XXXL-140x150cm, as per required
Product Code/Catalogue Number:	E1000, E1100, E1200, E1300, E1400, E1500
Basic UDI:	697549344ISOLATIONGOWNS6R
Classification Acc. to MDR Ax. VIII:	Class I, rule 1
Applied Standard & Common Specification:	EN ISO 14971: 2019 EN ISO 15223-1: 2016 EN 1041: 2008+A1: 2013 EN ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10: 2013 EN 62366-1: 2015
Conformity Assessment Procedure:	Annex II + Annex III of Regulation EU 2017/745 (MDR)

CE

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

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Yan Wei, General Manager

Anqing, China Aug. 1st, 2022

Digitally signed by Belan Irina
Date: 2022.09.13 01:46 EEST
Reason: MoldSign Signature
Location: Moldova

EU DECLARATION OF CONFORMITY

According to Regulation (EU) 2017/745 on Medical Devices

Manufacturer:	Carestone Medical & Protective Products Co., Ltd. 1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China
SRN:	CN-MF-000027756
European Representative	Luxus Lebenswelt GmbH Kochstr .1, 47877, Wilich, Germany Tel :0049-1715605732 E-mail: info.m@luxuslw.de
SRN:	DE-AR-000005110
Trade Name:	Disposable medical face mask
Product Name:	Disposable medical face mask
Specification:	17.5x9.5cm, 14.5x9cm
Product Code/Catalogue Number:	B2020, B3550, B7201
Basic UDI:	697549344MASKSTT
Classification According to MDR Ax. VIII:	Class I, rule 1
Applied Standard & Common Specification:	EN ISO 14971: 2019 EN ISO 15223-1: 2016 EN 1041: 2008+A1: 2013 EN ISO 10993-1:2020 EN ISO 10993-5:2009 EN ISO 10993-10: 2013 EN 62366-1: 2015 EN 14683:2019+AC: 2019
Conformity Assessment Procedure:	Annex II + Annex III of Regulation EU 2017/745 (MDR)

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Yan Wei, General manager

Anqing, China Aug. 1st, 2022