

# 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, Willich, Germany  
Tel :0049-1715605732 E-mail: info.m@luxuslw.de

SRN: DE-AR-000005110

Trade Name: Shoe Cover

Product Name: Shoe Cover

Specification: 15x39cm, 15x41cm  
17x41cm, 18x42cm, or as required

Product Code/Catalogue Number: L0500, L0550, L1000, L1050, L1500, L1550, L1700, L1750  
L3000, L3020, L3040, L3060, L3200, L3220, L3240, L3260

Basic UDI-DI: 697549344SHOECOVERS93

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

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



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 April 26, 2023



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Tel :0049-1715605732 E-mail: info.m@luxuslw.de

SRN: DE-AR-000005110

Trade Name: Isolation Gown

Product Name: Isolation Gown

Specification: S-110\*110cm, M-110x120cm, L-115x137cm, XL-120x140cm,  
XXL-130x150cm, XXXL-140x150cm, as per required

Product Code/Catalogue Number: H4200, H4300, H4400, H4500, H4600, H4700

Basic UDI-DI: 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)



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Yan Wei, General Manager

Anqing, China April 26, 2023



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|                                           |                                                                                                                                                                                        |
|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer:                             | Carestone Medical & Protective Products Co., Ltd.<br>1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China                                                              |
| SRN:                                      | CN-MF-000027756                                                                                                                                                                        |
| European Representative                   | Luxus Lebenswelt GmbH<br>Kochstr .1, 47877, Willich, Germany<br>Tel :0049-1715605732 E-mail: info.m@luxuslw.de                                                                         |
| SRN:                                      | DE-AR-000005110                                                                                                                                                                        |
| Trade Name:                               | Face mask with shield                                                                                                                                                                  |
| Product Name:                             | Face mask with shield                                                                                                                                                                  |
| Specification:                            | 17.5x9.5cm                                                                                                                                                                             |
| Product Code/Catalogue Number:            | B4000 (ear-loop) B4100 (tie-on)                                                                                                                                                        |
| Basic UDI-DI:                             | 697549344MASKSTT                                                                                                                                                                       |
| Classification According to MDR Ax. VIII: | Class I, rule 1                                                                                                                                                                        |
| Applied Standard & Common Specification:  | EN ISO 14971: 2019<br>EN ISO 15223-1: 2016<br>EN 1041: 2008+A1: 2013<br>EN ISO 10993-1:2020 EN ISO 10993-5:2009<br>EN ISO 10993-10: 2013<br>EN 62366-1: 2015<br>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 June 11, 2024



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

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|-------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Manufacturer:                             | Carestone Medical & Protective Products Co., Ltd.<br>1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China                                                              |
| SRN:                                      | CN-MF-000027756                                                                                                                                                                        |
| European Representative                   | Luxus Lebenswelt GmbH<br>Kochstr .1, 47877, Willich, Germany<br>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-DI:                             | 697549344MASKSTT                                                                                                                                                                       |
| Classification According to MDR Ax. VIII: | Class I, rule 1                                                                                                                                                                        |
| Applied Standard & Common Specification:  | EN ISO 14971: 2019<br>EN ISO 15223-1: 2016<br>EN 1041: 2008+A1: 2013<br>EN ISO 10993-1:2020 EN ISO 10993-5:2009<br>EN ISO 10993-10: 2013<br>EN 62366-1: 2015<br>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 April 26, 2023



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Kochstr .1, 47877, Willich, Germany  
Tel :0049-1715605732 E-mail: info.m@luxuslw.de

SRN: DE-AR-000005110

Trade Name: Caps

Product Name: Caps

Specification: 17", 18", 19", 20", 21", 24", 64\*12cm, S, M, L

Product Code/Catalogue Number: A0500, A1000, A1100, A1200, A1300, A1500  
A2000, A2060, A2085  
A2300, A2400

Basic UDI-DI: 697549344CAPSQS

Classification According to MDR Ax. VIII: Class I, rule 1

Applied Standard & Common Specification: EN ISO 14971: 2019 EN ISO 15223-1: 2016  
EN ISO 1041:2008+A1: 2013 EN ISO 10993-1:2020  
EN ISO 10993-5:2009 EN ISO 10993-10: 2013  
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Yan Wei, General Manager

Anqing, China April 26, 2023