



EC Declaration of Conformity

Manufacturer

Manufacturer: CARESTONE MEDICAL & PROTECTIVE PRODUCTS CO., LTD
Address: 1.3 Sq. Km. Industrial Gardon, Anqing Development Zone, Anhui, China

EU Representative

Name: LiKing GmbH
Address: Fraunhofer StraBe 7, 04178 Leipzig

Product

Name: Surgical Gown

Type: S, M, L, XL, XXL, XXXL

SRN: ---

Basic UDI-DI: ---

Classification: The medical device has been assigned to class I rule1 according to Annex VIII of the Medical Device Regulation(EU) 2017/745.

Conformity Assessment Route: Annex II+III

We confirm our product can meet the requirement of Medical Device Regulation and the following harmonized 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

EN 62366-1:2015

LIKING GmbH

(Autorisiert bei SPICA)

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YanWei / *Manager*
signature, Position