



## EU Declaration of Conformity

According to ANNEX IV of the Medical Device Regulation (EU) 2017/745

Manufacturer: **Exact Medical Manufacturing, Inc**  
No.21 QingJiang Road,Xinbei District  
213000 Changzhou,Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

SRN of the Manufacturer: CN-MF-000001406

Authorised Representative: Exact Medical Manufacturing B.V.  
Kerkstraat 35  
5253 AN NIEUWKUIJK  
THE NETHERLANDS

SRN of the Authorised Rep.: NL-AR-000000452

Product Name: Sterile Equipment Cover

Product Code: **See Appendix I**

Basic UDI-DI of Product: **See Appendix I**

EMDN Code: **See Appendix I**

Classification (MDR, Annex VIII): **Is, rule 1**

Conformity Assessment Procedure: **Annex XI Part A**

We (manufacturer) herewith state that the above-mentioned product is in conformity with the following Medical Device Regulation and Product Standards. We are solely responsible for the EU declaration of conformity.

The applicable Medical Device Regulation and Product Standards:

Medical Device Regulation (EU) 2017/745

EN 13795-1:2019

Notified Body: TÜV SÜD Product Service GmbH  
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123

(EC) Certificate(s): G21 098746 0003

Expire date of the Certificate: 2027-03-17

Signature:

Name: Ms. Elaine

Position: Management Representative (The person responsible for regulatory compliance)

Place, Date of Issue: Changzhou, Friday, November 25, 2022



**Appendix I**

<b>Product Name</b>	<b>Product Code</b>	<b>Basic UDI-DI</b>	<b>EMDN code</b>
Sterile Equipment Cover	E6783	697508570EC30J8	T030199
Sterile Equipment Cover	E6784	697508570EC30J8	T030199
Sterile Equipment Cover	E6785	697508570EC30J8	T030199