



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 IX Chapters I and III**

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): G11 098746 0005

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, August 1, 2025



Appendix I

Code	Description	Basic UDI-DI	EMDN code
E6783	Remote control cover 180x10cm - 70"x4"	697508570EC30J8	T030199
E6784	Cover IID 168x60cm	697508570EC30J8	T030199
E6785	Sterile Cover	697508570EC30J8	T030199