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 30 April 2025

Appendix I

Product Name	Product Code	Basic UDI-DI	EMDN code
Sterile Equipment Cover	E6006	697508570EC04J7	T030199