# EU Declaration of Conformity

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

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|---|---|
| Manufacturer: | **Exact Medical Manufacturing, Inc**<br>No.21 QingJiang Road,Xinbei District<br>213000 Changzhou,Jiangsu Province<br>PEOPLE'S REPUBLIC OF CHINA |
| SRN of the Manufacturer: | CN-MF-000001406 |
| Authorised Representative: | Exact Medical Manufacturing B.V.<br>Kerkstraat 35<br>5253 AN NIEUWKUIJK<br>THE NETHERLANDS |
| SRN of the Authorised Rep.: | NL-AR-000000452 |
| Product Name: | Non-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): **I, 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

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| Signature: |  |
| Name: | Ms. Elaine |
| Position: | Management Representative (The person responsible for regulatory compliance) |
| Place, Date of Issue: | Changzhou, September 3, 2024 |

## Appendix I

| Code | Description | Basic UDI-DI | EMDN code |
|---|---|---|---|
| E6565N | Foot Switch Cover with drawstring 41x46x8cm - 16"x18"x3" | 697508570EC17JG | T030199 |
| E6566N | Foot Switch Cover with adhesive 36x76cm - 14"x30" | 697508570EC17JG | T030199 |
| E6567N | Foot Switch Cover with drawstring and adj. 61x46cm - 24"x18" | 697508570EC17JG | T030199 |
| E6568N | Foot Switch Cover with drawstring 76x66cm - 30"x26" | 697508570EC17JG | T030199 |
| E6569N | Foot Switch Cover, drawstring, and adjuster 56x51cm - 22"x20" | 697508570EC17JG | T030199 |