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:	Intraoperative Probe cover
Product Code:	**See Appendix I**
Basic UDI-DI of Product:	**See Appendix I**
EMDN Code:	**See Appendix I**

Classification (MDR, Annex VIII): **IIa, rule 6**

Conformity Assessment Procedure: **Annex IX excluding chapter II**

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):	G10 098746 0008
Expire date of the Certificate:	2030-01-16
Signature:	 _____
Name:	Ms. Elaine Lu
Position:	Management Representative (The person responsible for regulatory compliance)
Place, Date of Issue:	Changzhou, October 2, 2025

Appendix I

Code	Description	Basic UDI-DI	EMDN
E6300	Probe Cover, PE, Elastic bands 5x61cm - 2"x24"	697508570EC07JD	T030102
E6301	Probe Cover, Cordless PU, 9x37cm - 4"x15"	697508570EC07JD	T030102
E6302	Probe Cover, PE, Elastic bands 10x61cm - 4"x24"	697508570EC07JD	T030102
E6303	Probe Cover, PE, Elastic bands 10x122cm - 4x48"	697508570EC07JD	T030102
E6306	Probe Cover, PE, Elastic bands 13x122cm - 5"x48"	697508570EC07JD	T030102
E6308	Probe Cover, PE, Square Tip 15x152cm - 6"x60"	697508570EC07JD	T030102
E6310	Probe Cover, PE, Elastic bands 13x244cm - 5"x96"	697508570EC07JD	T030102
E6319	Probe Cover, PE, Elastic bands 15x61cm - 6"x24"	697508570EC07JD	T030102
E6320	Probe Cover, VIP film, Elastic bands 15x61cm - 6"x24"	697508570EC07JD	T030102
E6321	Probe Cover, PE, Elastic bands 15x91cm - 6"x36"	697508570EC07JD	T030102
E6322	Probe Cover, PE, Elastic bands 15x122cm - 6"x48"	697508570EC07JD	T030102
E6326	Probe Cover, PE, Elastic bands 15x244cm - 6"x96"	697508570EC07JD	T030102
E6328	Probe Cover, PE, Tape Tip, 18x28cm - - 7"x11"	697508570EC07JD	T030102
E6328G	Probe Cover, PE, Tape Tip, Gel, 18x28cm - 7"x11"	697508570EC07JD	T030102
E6329	Probe Cover, PE, Tape Tip, 18x40cm - 7"x16"	697508570EC07JD	T030102
E6329G	Probe Cover, PE, Tape Tip, Gel, 18x40cm - 7"x16"	697508570EC07JD	T030102
E6330	Probe Cover, PE, Gel and Elastic bands 18x61cm - 7"x24"	697508570EC07JD	T030102
E6331	Probe Cover, PE, Gel and Elastic bands 18x79cm - 7"x31"	697508570EC07JD	T030102
E6332	Probe Cover, PE, Tape Tip, 18x80cm - 7"x31"	697508570EC07JD	T030102
E6332G	Probe Cover, PE, Tape Tip, Gel, 18x80cm - 7"x31"	697508570EC07JD	T030102
E6333	Probe Cover, PE, Gel and Elastic bands 18x91cm - 7"x36"	697508570EC07JD	T030102
E6334	Probe Cover, PE, Tape Tip, 18x119cm - 7"x47"	697508570EC07JD	T030102
E6334G	Probe Cover, PE, Tape Tip, Gel, 18x119cm - 7"x47"	697508570EC07JD	T030102
E6335	Probe Cover, PE, Elastic bands 18x127cm - 7"x50"	697508570EC07JD	T030102
E6336	Probe Cover, PE, Tape Tip, 18x127cm - 7"x50"	697508570EC07JD	T030102
E6336G	Probe Cover, PE, Tape Tip, Gel, 18x127cm - 7"x50"	697508570EC07JD	T030102
E6337	Probe Cover, PE, Elastic bands 18x160cm - 7"x63"	697508570EC07JD	T030102
E6338	Probe Cover, PE, Tape Tip, 18x160cm - 7"x63"	697508570EC07JD	T030102
E6338G	Probe Cover, PE, Tape Tip, Gel, 18x160cm - 7"x63"	697508570EC07JD	T030102
E6339	Probe Cover, PE, Tape Tip, 18x249cm - 7"x98"	697508570EC07JD	T030102
E6339G	Probe Cover, PE, Tape Tip, Gel, 18x249cm - 7"x98"	697508570EC07JD	T030102
E6340	Probe Cover, PE, Elastic bands 23x61cm - 9"x24"	697508570EC07JD	T030102
E6341	Probe Cover, VIP film, Gel and El. bands 13x244cm - 5"x96"	697508570EC07JD	T030102
E6343	Probe Cover, VIP film, Gel, LF tip, El. bands 13x244cm 5"x96"	697508570EC07JD	T030102
E6344	Probe Cover, VIP film, Gel and El. bands 13x122cm - 5"x48"	697508570EC07JD	T030102
E6345	Probe Cover, VIP film, Gel and El. bands 8x244cm - 3"x96"	697508570EC07JD	T030102
E6346	Probe Cover, VIP film, Gel and El. bands 13x61cm - 5"x24"	697508570EC07JD	T030102
E6347	Probe Cover, PE, Square Tip, 15x200cm - 6"x79"	697508570EC07JD	T030102
E6349	Probe Cover, PE, Tape Tip, Elastic bands 12x25cm - 5"x10"	697508570EC07JD	T030102

Code	Description	Basic UDI-DI	EMDN
E6349G	Probe Cover, PE, Tape Tip, Gel, El. bands 12x25cm - 5"x10"	697508570EC07JD	T030102
E6350	Probe Cover, VIP film, Elastic bands 15X122cm - 6"x48"	697508570EC07JD	T030102
E6351	Probe Cover, VIP film, Elastic bands 15x244cm - 6x96"	697508570EC07JD	T030102
E6355	Probe Cover, VIP film and Elastic bands 5x61cm - 2"x24"	697508570EC07JD	T030102
E6356	Universal Gamma Probe Cover 8x244cm - 3"x 96"	697508570EC07JD	T030102
E6357	Probe Cover, PE, Tape 18x230cm - 7"x91"	697508570EC07JD	T030102
E6400	Probe Cover, PE, Gel and Elastic bands 5x61cm - 2"x24"	697508570EC07JD	T030102
E6401	Probe Cover, VIP film, Gel and Elastic bands 5x61cm - 2"x24"	697508570EC07JD	T030102
E6402	Probe Cover, PE, Gel and Elastic bands 10x61cm - 4"x24"	697508570EC07JD	T030102
E6403	Probe Cover, VIP film, Gel and Elastic bands 10x61cm -4"x24"	697508570EC07JD	T030102
E6407	Probe Cover, VIP film, Gel and Elastic bands 10x122cm - 4x48	697508570EC07JD	T030102
E6410	Probe Cover, PE, Gel and Elastic bands 10x124cm - 4"x49"	697508570EC07JD	T030102
E6412	Probe Cover, PE, Gel and Elastic bands 10x244cm - 4"x96"	697508570EC07JD	T030102
E6413	Probe Cover, VIP film, Gel and Elastic bands 10x244cm - 4x96	697508570EC07JD	T030102
E6415	Probe Cover, PE, Gel and Elastic bands 13x122cm - 5"x48"	697508570EC07JD	T030102
E6417	Probe Cover, PE, Gel, tape and El. bands 13x150cm - 5"x59"	697508570EC07JD	T030102
E6418	Probe Cover, PE, Gel and Elastic bands 13x244cm - 5"x96"	697508570EC07JD	T030102
E6427	Probe Cover, PE, Gel and Elastic bands 15x61cm - 6"x24"	697508570EC07JD	T030102
E6428	Probe Cover, VIP film, Gel, Elastic bands 15x61cm - 6"x24"	697508570EC07JD	T030102
E6430	Probe Cover, PE, Gel and Elastic bands 15x91cm - 6"x36"	697508570EC07JD	T030102
E6431	Probe Cover, PE, Gel and Elastic bands 15x122cm - 6"x48"	697508570EC07JD	T030102
E6432	Probe Cover, VIP Film, Gel, Elastic bands 15x122cm - 6"x48"	697508570EC07JD	T030102
E6433	Probe Cover, VIP Film, Gel, Elastic bands 15x147cm - 6"x58"	697508570EC07JD	T030102
E6434	Probe Cover, PE, Gel and Elastic bands 15x244cm - 6"x96"	697508570EC07JD	T030102
E6435	Probe Cover, VIP Film, Gel, Elastic bands 15x244cm - 6"x96"	697508570EC07JD	T030102
E6437	Probe Cover, PE, Elastic bands 18x61cm - 7"x24"	697508570EC07JD	T030102
E6439	Probe Cover, PE, Gel and Elastic bands 18x127cm - 7"x50"	697508570EC07JD	T030102
E6440	Probe Cover, PE, Gel and Elastic bands 18x160cm - 7"x63"	697508570EC07JD	T030102
E6441	Probe Cover, PE, Gel and Elastic bands 18x244cm - 7"x96"	697508570EC07JD	T030102
E6442	Probe Cover, PE, Gel and Elastic bands 23x61cm - 9"x24"	697508570EC07JD	T030102
E6446	Probe Cover, VIP film, Gel, El. b., Cardb. 15x61cm - 6"x24"	697508570EC07JD	T030102
E6447	Probe Cover, VIP film, Gel, El. b., Cardb. 15x122cm - 6"x48"	697508570EC07JD	T030102
E6448	Probe Cover, VIP film, Gel, El. b., Cardb. 15x244cm - 6"x96"	697508570EC07JD	T030102
E6450	Probe Cover, VIP film, Gel, Elastic bands 15x147cm-6"x58"	697508570EC07JD	T030102
E6451	Probe Cover, VIP film, Gel, Elastic bands 15x91cm - 6"x36"	697508570EC07JD	T030102
E6452	Probe Cover PU-Film, Gel, Tape and El. bands, 13-5.5x63cm	697508570EC07JD	T030102
E6471	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 10x61cm - 4" x 24"	697508570EC07JD	T030102
E6472	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 13x61cm - 5" x 24"	697508570EC07JD	T030102
E6473	Adhesive Probe Cover, VIP-Film, Gel & Bands - 15x61cm - 6" x 24"	697508570EC07JD	T030102
E6474	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 10x122cm - 4" x 48"	697508570EC07JD	T030102
E6475	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 13x122cm - 5" x 48"	697508570EC07JD	T030102
E6476	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 10x244cm - 4" x 96"	697508570EC07JD	T030102

Code	Description	Basic UDI-DI	EMDN
E6477	Adhesive Probe Cover, VIP-Film, 3D Box Tip, Gel & Elastic Bands, 13x244cm - 5" x 96"	697508570EC07JD	T030102
E6479	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 10x61cm - 4" x 24"	697508570EC07JD	T030102
E6480	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 13x61cm - 5" x 24"	697508570EC07JD	T030102
E6481	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 10x122cm - 4" x 48"	697508570EC07JD	T030102
E6482	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 13x122cm - 5" x 48"	697508570EC07JD	T030102
E6457	Adhesive Probe Cover, VIP-Film, Gel & Bands - 15x122cm - 6" x 48"	697508570EC07JD	T030102
E6483	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 10x244cm - 4" x 96"	697508570EC07JD	T030102
E6484	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 13x244cm - 5" x 96"	697508570EC07JD	T030102
E6478	Adhesive Probe Cover, VIP-Film, Gel & Bands - 15x244cm - 6" x 96"	697508570EC07JD	T030102
E6485	Adhesive Probe Cover, VIP-Film, Straight End with Gel & Bands - 15x244cm - 6" x 96"	697508570EC07JD	T030102
E7108	Intraoperative Probe Cover, Round Tip, w/ Gel and Elastic Bands, 13x244cm - 5"x96"	697508570EC07JD	T030102
E7109	Intraoperative Probe Cover, Angled Tip, w/ Gel and Elastic Bands, 13x244cm - 5"x96"	697508570EC07JD	T030102
E7110	Intraoperative Probe Cover, Small T-Tip, w/ Gel and Elastic Bands, 15x244cm - 6"x96"	697508570EC07JD	T030102
E7111	Intraoperative Probe Cover, Large T-Tip, w/ Gel and Elastic Bands 15x244cm - 6"x96"	697508570EC07JD	T030102