



## EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III  
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

**No. G11 098746 0005 Rev. 00**

### Manufacturer:

### Exact Medical Manufacturing, Inc

No.21 Qingjiang Road, Xinbei District  
213000 Changzhou, Jiangsu Province  
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000001406

### Authorized Representative:

Exact Medical Manufacturing B.V.  
Kerkstraat 35, 5253 AN NIEUWKUIJK, THE NETHERLANDS

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:

- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G11 098746 0005 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:G11 098746 0005 Rev. 00)

**Report No.:** SH22117801

**Preceding Certificate No.:** G21 098746 0003 Rev. 00

**Valid from:** 2023-05-25

**Valid until:** 2027-03-17

Christoph Dicks  
Head of Certification/Notified Body

**Issue date:** 2023-05-25



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**Classification:** Class I

**Device Group:** T02010101 - INCISION DRAPES, WITHOUT ANTIBACTERIAL AGENT  
T020199 - SURGICAL DRAPES - OTHER  
T020401 - STANDARD SURGICAL GOWNS  
T020402 - REINFORCED SURGICAL GOWNS  
T030101 - COVER CAPS, INSTRUMENTS AND EQUIPMENT  
T030102 - COVER SHEATHS, INSTRUMENTS AND EQUIPMENTS  
T030199 - COVERS, INSTRUMENTS AND EQUIPMENT - OTHER

**Device Properties:** MDS 1005.1 - Ethylene Oxide sterilization

**The validity of this certificate depends on conditions and/or is limited to the following:** -none-

### Revision History:

Rev.	Dated	Report	Description
00	2023-05-25	SH22117801	Initial issuance