

# EU Quality Management System Certificate

Regulation (EU) 2017/745, Annex IX Chapter I and III

## MDR 756375 R000

**Manufacturer:** Surgnova Healthcare Technologies (Zhejiang) Co., Ltd

**Address:**

No.1 Xinxing Yilu Road  
Emerging Industrial  
Cluster Area  
Zonghan Subdistrict  
Cixi City  
Zhejiang  
315301  
China

**Single Registration Number:** CN-MF-000014087

**EU Authorised Representative:** Shanghai International Holding Corp. GmbH (Europe)

**Address:**

Eiffestrasse 80  
20537 Hamburg  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class III devices, and Class IIb implantable devices that are not considered well-established technologies as specified in Article 52(4) an additional Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

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, Senior Vice President Global Regulatory & Quality

First Issue Date: **2023-06-02**

Current Issue Date: **2024-04-17**

Starting Validity Date: **2024-04-17**

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### Device Schedule: Class III and Class IIb devices

Class IIb	Intended purpose
Ultrasonic surgical & Electrosurgical system, including Ultrasonic Surgical & Electrosurgical Generator, sterile Ultrasonic Scalpel, Electrosurgical Pencil, Electrosurgical Electrode, Laparoscopic Electrode, and Bipolar Coagulation Forceps.	The product includes electrosurgical and ultrasonic scalpel. The electrosurgical is mainly used to cut and coagulate human soft tissue in clinical operations. The ultrasonic scalpel is used to cut, dissect and coagulate tissue; it may be applied for sealing vessels up to and including 7 mm in diameter; it is indicated for use in open and endoscopic general surgical procedures, and other procedures where bleeding control and minimal thermal injury to tissue are desired.
Electroporation System, including Electroporation Power Generator and sterile Electroporation Probes	The Electroporation System is intended for surgical ablation of soft tissue (of pancreas, liver, prostate) by irreversible electroporation.
Microwave Ablation System, including Microwave Ablation Generator, sterile Microwave Ablation Electrode Kits, and sterile Temperature Probe	The Microwave Ablation System is intended for the use in percutaneous, laparoscopic and intraoperative coagulation and ablation of soft tissue.
Radiofrequency Ablation System, including Radiofrequency Generator, sterile Radiofrequency Ablation Electrode Kits, and sterile Temperature probe	The Radiofrequency Ablation System is intended for the use in percutaneous, laparoscopic and intraoperative coagulation and ablation of soft tissue.

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### Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Ultrasonic Transducer	Class IIa
Electroporation Fixator support	Class IIa
Gas Insufflator, including Gas Insufflator Unit, High-pressure Gas Pipe, and sterile Insufflation Tubing Set	Class IIa



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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2023-06-02	3508101	Issued
2023-11-23	30028579	Supplemented – Addition of Microwave Ablation System, including Microwave Ablation Generator, sterile Microwave Ablation Electrode Kits, and sterile Temperature Probe; Radiofrequency Ablation System, including Radiofrequency Generator, sterile Radiofrequency Ablation Electrode Kits, and sterile Temperature probe; Gas insufflator, including Gas Insufflator Unit, High-pressure Gas Pipe, and sterile Insufflation Tubing Set. Amended- Change of Intended purpose to “up to and including 7 mm in diameter”
Current	30124551	Amended- Change of legal manufacture name and address to correct display errors: Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. No.1 Xinxing Yilu Road Emerging Industrial Cluster Area Zonghan Subdistrict Cixi City Zhejiang 315301 China

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