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| Status | See watermark |
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# Project File

## Microwave Ablation System
## EU Declaration of Conformity

Project Name： Dorado
Document number： DOC120004-107
Version： Rev 10



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Be sure to use the latest controlled version and to comply with the requirements of the Document Control Procedure ！

## Review

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| Quality Assurance Engineer | Su Jie | See electronic signature page | See electronic signature page |
| RA Manager | Wang Suqin | See electronic signature page | See electronic signature page |
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## Approval

| Role | Name | Signature | Date |
|---|---|---|---|
| QA&RA Director | Ma Guofang | See electronic signature page | See electronic signature page |
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# Revision Control History

| Date | Author | Rev. | Details of Changes |
|---|---|---|---|
| 2018/05/24 | Zhao Jingru | Rev 1 | Initial release. |
| 2019/03/13 | Zhao Jingru | Rev 2 | Update the Notified Body information |
| 2019/09/02 | Mi Jingjing | Rev 3 | Update the European Representative |
| 2020/11/23 | He Juan | Rev 4 | Add the model of Foot Switch to the model list |
| 2020/12/25 | He Juan | Rev 5 | Add 16G MWA Electrode;<br>Modify incomplete description of material in Appendix A. |
| 2021/09/29 | Wu Jiawei | Rev 6 | Update the standard version and meet the requirement of MDR. |
| 2022/02/16 | Wu Jiawei | Rev 7 | 1.Add SRN, and intended purpose;<br>2. Delete the models “SS-MWA-1536P, SS-MWA-2536P, SS-MWA-0723P, SS-MWA-2036P”. |
| 2023/02/06 | Hao Yingshuai | Rev8 | 1. Updated the description of intended purpose.<br>2. Update the specific name of notified body. |
| 2023/11/23 | Zhang Shuiying | Rev9 | 1.Add the trade name Dophi<br>2.Add the classification of accessories<br>3.Add the “SRN：DE-AR-000000001” of European Representative<br>4. Update the standards<br>5. Signed by CEO Zhang Jindi |
| 2024/2/28 | Zhang Shuiying | Rev10 | Correct “Microwave Generator” to “Microwave Ablation Generator” in order to align with certificate MDR 756375 |

| EU DECLARATION OF CONFORMITY<br>TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES | | |
|---|---|---|
| Manufacturer | **Name** | Surgnova Healthcare Technologies (Zhejiang) Co., Ltd. |
| | **Address** | No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area, Zonghan subdistrict, Cixi City, Zhejiang, 315301 China |
| | **SRN** | CN-MF-000014087 |
| **Product Name** | | Microwave Ablation System |
| **Trade name** | | Dophi |
| **Model** | | Microwave Ablation Generator: M150E |
| | | Microwave Ablation Electrode Kits: See Appendix A |
| | | Temperature Probe: SS-TP18G-20 |
| | | Foot Switch: SJ-B02 |
| **Intended Purpose** | | The Microwave Ablation System is intended for the use in percutaneous, laparoscopic and intraoperative coagulation and ablation of soft tissue. |
| **Basic UDI-DI** | | 69723047500026R |
| **Classification** | | Microwave Ablation System, Class IIb, Rule 9, Annex VIII, Regulation (EU) 2017/745 |
| | | Microwave Ablation Generator, Class IIb, Rule 9, Annex VIII, Regulation (EU) 2017/745 |
| | | Microwave Ablation Electrode Kits, Class IIb, Rule 9, Annex VIII, Regulation (EU) 2017/745 |
| | | Temperature Probe, Class IIb, Rule 9, Annex VIII, Regulation (EU) 2017/745 |
| | | Foot Switch, Class I, Rule 13, Annex VIII, Regulation (EU) 2017/745 |
| **Conformity assessment procedure** | | Chapters I and III, Annex IX, Regulation (EU) 2017/745 |
| WE, Surgnova Healthcare Technologies (Zhejiang) Co., Ltd., HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES; | | |
| ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE EU DECLARATION OF CONFORMITY IS ISSUED UNDER THE SOLE RESPONSIBILITY OF THE MANUFACTURER. | | |
| STANDARDS APPLIED: Refer to the Appendix B. | | |
| **Notified Body** | **Name** | BSI Group The Netherlands B.V. |
| | **Address** | Say Building , John M, Keynesplein 9, 1066 EP Amsterdam, The Netherlands |
| | **Identification number** | CE 2797 |
| EC REP<br>**European Representative** | **Name** | Shanghai International Holding Corp Gmbh ( Europe ) |
| | **Address** | Eiffestrasse 80, 20537 Hamburg Germany |
| | **SRN** | DE-AR-000000001 |
| **(EC) Certificate number** | | MDR 756375 |
| **Place, Date of Declaration** | | Zhejiang, 02/28/2024 |
| **Signature** | | |
| **Name of Authorized Signatory** | | |
| **Position Held in Company** | | CEO |

**Appendix A:** Model of Microwave Ablation Electrode Kits

| Model | Material | Out Diameter | Needle Length |
|---|---|---|---|
| SS-MWA-2531C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 250mm |
| SS-MWA-2526C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 250mm |
| SS-MWA-2031C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 200mm |
| SS-MWA-2026C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 200mm |
| SS-MWA-1531C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 150mm |
| SS-MWA-1526C | 304SS, polyethlene terephthalate, ceramics tube and ceramics tip | 2.08mm | 150mm |
| SS-MWA-2525P | 304SS, polyethlene terephthalate, PEEK tube and ceramics tip | 1.6mm | 250mm |
| SS-MWA-2025P | 304SS, polyethlene terephthalate, PEEK tube and ceramics tip | 1.6mm | 200mm |
| SS-MWA-1525P | 304SS, polyethlene terephthalate, PEEK tube and ceramics tip | 1.6mm | 150mm |

## Appendix B: Standards Applied

| NO. | Standards Reference | Title |
|---|---|---|
| 1. | ASTM F1980 - 2016 | Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices |
| 2. | EN ISO 20417: 2021 | Medical devices - Information to be supplied by the manufacturer |
| 3. | EN 60601-1:2006/A2:2021 | Medical electrical equipment—Part 1: General requirements for basic safety and essential performance |
| 4. | EN 60601-1-2:2015 | Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests |
| 5. | EN 60601-2-6:2015/A1:2016 | Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment |
| 6. | EN 62304:2006/A1:2015 | Medical device software—Software life cycle processes |
| 7. | EN 62366-1:2015/A1:2020 | Medical devices—Application of usability engineering to medical devices |
| 8. | EN 868-5:2018 | Packaging for terminally sterilized medical devices. Sealable pouches and reels of porous and plastic film construction. Requirements and test methods |
| 9. | EN ISO 10993-1:2020 | Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process—Technical Corrigendum 1 |
| 10. | EN ISO 10993-10:2013 | Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization |
| 11. | EN ISO 10993-5:2009 | Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity |
| 12. | EN ISO 10993-7:2008/A1:2022 | Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals |
| 13. | EN ISO 10993-10:2013 | Biological evaluation of medical devices—Part 10: Tests for irritation and skin sensitization |
| 14. | EN ISO 10993-11:2018 | Biological evaluation of medical devices — Part 11: Tests for systemic toxicity |
| 15. | EN ISO 11135:2014/A1: 2019 | Sterilization of health care products -- Ethylene oxide -- Requirements for the development, validation and routine control of a sterilization process for medical devices |
| 16. | EN ISO 11138-2:2017 | Sterilization of health care products—Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes |
| 17. | EN ISO 11607-1:2020 | Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems |
| 18. | EN ISO 11607-2:2020 | Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes |
| 19. | EN ISO 13485:2016/A11:2021 | Medical devices—Quality management systems—Requirements for regulatory purposes |
| 20. | EN ISO 14971:2019 | Medical devices—Application of risk management to medical devices |
| 21. | EN ISO 15223-1:2021 | Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| 22. | EN ISO 780:2015 | Packaging - Distribution packaging - Graphical symbols for handling and storage of packages |

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|---|---|
| 文件编号<br>Documnet Number | DOC120004-107 |
| 文件名称<br>Title | 微波消融系统CE Declaration of Conformity |
| 版本<br>Revision | REV10 |
| 生效日期/旧版作废日期<br>Release Date/Obsolete Date | 2024-03-01 08:01:39 |
| 文件上传人<br>Documnet Creator | |

| 路径编号<br>Route | 审批人<br>Signer | 状态<br>Status | 日期<br>Completion Date |
|---|---|---|---|
| DCC#193982 | | 已批准 | 2024-03-01 08:01:37 |
| DCC#193982 | | 已批准 | 2024-02-29 15:37:14 |
| DCC#193982 | | 已审核 | 2024-02-29 14:33:42 |
| DCC#193982 | | 已审核 | 2024-02-28 16:15:58 |

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