TOOsonix

CE

DECLARATION OF CONFORMITY

TOOsonix A/S
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SRN: DK-MF-000014211

ensure and declare under our sole responsibility that the medical device:

Name of medical device:	System ONE-M
Reference Number:	S02
Basic UDI-DI:	57000021926SysONE-MRZ
Risk Classification / Rule	Class IIa / Rule 9
Intended purpose:	System ONE-M is intended for treatment of the human epidermis and dermis layers by administering high-intensity focused ultrasound (HIFU) doses to small and confined volumes in the human skin

that bear the CE mark, is according to the General Safety and Performance Requirements defined within Annex I of the Medical Device Regulation – Regulation EU 2017/745 of the European Parliament and the Council of 5 April 2017, and with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München, Germany
Notified Body ID number:	0123
EC Certificate:	G10 004086 0003 REV. 00
Conformity Assessment Proc.:	Annex XI Part 10 of MDR 2017/745

List of equipment and harmonized standards are included with this declaration

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Issued by:

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PRRC

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Managing Director

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LIST OF EQUIPMENT

TOOsonix Part#	REF#	UDI-DI (GTIN)	Product Description	Product Type	Product Category
System ONE-M REF S02. HIFU device for dermatological treatment - Purchased for specific variant					
9-01-002	S02	5700002192608	System ONE-M - Schuko Plug	Medical Device Class IIa	Medical Device
9-01-004	S02	5700002192653	System ONE-M - DK Plug		
9-01-005	S02	5700002192660	System ONE-M - CH Plug		
Handpiece REF H03. Applied Part with varying Nominal Focal Depth - Purchased with device - Sold separately as renewals after expiry.					
9-10-004	H03	5700002192615	Handpiece ONE-M - NFD 0.8 mm	Medical Device Class IIa	Medical Device (Applied Part)
9-10-005	H03	5700002192622	Handpiece ONE-M - NFD 1.3 mm		
9-10-006	H03	5700002192639	Handpiece ONE-M - NFD 1.8 mm		
9-10-007	H03	5700002192646	Handpiece ONE-M - NFD 2.3 mm		

APPLICABLE MAIN STANDARDS

Standard	Title
IEC 60601-1:2012	Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014	Medical Electrical Equipment - General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 62304:2015	Medical device software - Software life-cycle processes
IEC 62366-1:2015/COR1:2016	Medical devices – Application of usability engineering to medical devices
IEC 60601-2-62:2015	Medical electrical equipment - Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment
EN/ISO 10993-1:2018	Biological evaluation of medical devices
EN ISO 14971:2019	Medical devices — Application of risk management to medical devices
Common Specifications	None

Please note: Collateral standards and guidance documents are used to verify conformity to main standards.