



DECLARATION OF CONFORMITY

This document hereby declares that the designated products below conform to all applicable requirements of the Directive 93/42/EEC of June 14th 1993 amendment by Directive 2007/47/EC.

Brand name: **TOOsonix System ONE-M**

Products:

Product Name	REF Num	SN format	Classification
System ONE-M	S02	XXXX	Class I
Handpiece ONE-M	H03	XXXXX	Class I

Legal Manufacturer: TOOsonix A/S
 Agern Allé 1
 DK-2970 Hoersholm
 Denmark
www.toosonix.com

Country of Origin: Denmark

Indication for use: System ONE-M is intended for non-invasive tattoo removal and other aesthetic HIFU treatment of the human skin such as solar lentiginos (liver spots), angiomas (cherry spots), telangiectasia (spider veins) and fine-line wrinkles.
(please see product IFU for full details)

Conformity Route: Annex VII

Issue Date: June 18th 2020

Issued by:

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