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## STATEMENT OF CONFORMITY

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This document hereby certifies that the designated product below been tested and evaluated at an accredited laboratory to be in compliance with the applicable harmonized standards below. The equipment is labelled with the CE mark as an electrical equipment for laboratory use.

Product: TOOsonix System ONE-R

Model Numbers: S03-XXXX (HIFU System)  
H04-XXXXX (HIFU Handpieces for S03)

Manufacturer: TOOsonix A/S  
Agern Allé 1  
DK-2970 Horsholm  
Denmark

Country of Origin: Denmark

Applicable Standards : EN 61010-1:2010  
EN 61326-1:2013  
EN 55011:2016-05+A1:2017-06 - Class A, Group 2  
EN 61000-3-2:2014  
EN 61000-3-3:2013  
EN 61000-4-3:2007+A1:2008+A2:2011+IS1:2009  
EN 61000-4-4:2013  
EN 61000-4-5:2014  
EN 61000-4-6:2014  
EN 61000-4-11:2004

One sample of the designated product has been tested and evaluated at an accredited test laboratory. The following test reports document full details of the conducted tests and can be reviewed at audits:

YG0081e - Safety Requirements for Laboratory Equipment  
BS3171- EMC Immunity Tests - RF Field Immunity Tests  
YZ0016p - RF Disturbance Characteristics Tests  
YK0024e - EMC Immunity Tests - Electrostatic Discharge Immunity  
YK0023e - EMC Immunity Tests - Voltage var. and interruption tests

Issued by:



Torsten Bove  
Managing Director



Tomasz Zawada  
Managing Director

*The verification is based on evaluation of one sample of above-mentioned products. It does not imply an assessment of the whole production.*

*Dermatological Therapy*

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