

Hoersholm Denmark, June 4th 2020

ROHS Declaration

With reference to:

Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011.
On the restriction of the use of certain hazardous substances in electrical and electronic equipment
(also known as the ROHS II directive)

We hereby declare that:

Name	TOOsonix System ONE-M
System Ref.	S02-XXXX
Handpiece Ref.	H03-XXXXX

do not contain any of the substances restricted by this regulation above the stipulated threshold values.

This declaration is based on information provided by our suppliers, to whom we have constant contact regarding substance restrictions and relevant legislation.

Please note:

The TOOsonix handpiece contains a small component for generation of HIFU signals. This component is manufactured from a material called Lead Zirconate Titanate (CAS no. 12626-81-2) as its main constituent. According to Annex III (7c pt I) and Annex UV (14) of the current directive, PZT is exempted from the substance prohibition.

According to current knowledge, the functionality and performance of the HIFU Handpiece cannot be achieved with any alternative substance or mixture of substances. Irrespective of this, we are monitoring opportunities to replace the component with another alternative as soon as feasible.

You are of course welcome to contact us for further information regarding this matter.

Yours sincerely,



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High Frequency Ultrasound Therapy