

Hoersholm Denmark, February 26<sup>th</sup> 2019

## REACH Declaration

With reference to:

Directive 1907/2006/EU of the European Parliament and of the Council of 18 December 2006, concerning the Registration, Evaluation, Authorization and Restriction of Chemicals

(also known as the REACH directive).

Under the definition of this directive, TOOsonix is a supplier of "articles" of the following:

|                       |                            |
|-----------------------|----------------------------|
| <b>Name</b>           | <b>TOOsonix System ONE</b> |
| <b>Model Ref.</b>     | <b>S01-XXX, S02-XXXX</b>   |
| <b>Handpiece Ref.</b> | <b>H01-XXXX, H02-XXXXX</b> |

and is therefore required to inform recipients if an article contains a Substance of Very High Concern (SVHC) in excess of 0.1% by weight.

The EU has announced an updated list of the candidate VHC chemicals. The list can be found at: [http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

Based on the material content certifications provided by TOOsonix's suppliers, none of these substances are present in the materials used in the TOOsonix products, packing, and shipping materials, with one exception.

The TOOsonix handpiece contains a single 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. The European Chemicals Agency, ECHA, has added this material to its list of the candidate SVHC chemicals as toxic for reproduction in accordance with Article 57c of the REACH directive (toxic for reproduction, Cat 1).

While the component is far less than 0.1% of the entire system, it is above the threshold weight of separate handpieces.

The relevant material is bound in a solid crystalline and insoluble form, and furthermore covered in a solid metallic electrode material. The material can therefore never be unintendedly released to the environment after the supplier's manufacturing process has been completed.

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.

TOOsonix will continue to monitor REACH requirements and notify customers of any change in article content.

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

Yours sincerely,



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*High Frequency Ultrasound Therapy*