

EC Declaration of Conformity

EC Declaration of Conformity Class I devices to Medical Devices Directive 93/42/EEC

Manufacturer: ULTRAGEL HUNGARY 2000 Kft.

Manufacturer's Address:

Seat of Manufacturer: 1023 Budapest, Bécsi út 4. Hungary

Factory of Manufacturer: 1211 Budapest, tekercselő u.12. Hungary

Device/s: Ultrasound gels,

Aquaultra Basic

Aquaultra Clear

Aquaultra Aloe

HYPERSCAN100

Aqua-LUB

Aqua-LUB20

EC Product Class: Class I in accordance with Annex IX, Rule 1.

Declaration of Conformity

Ultragel Hungary 2000 Kft. declares that Ultrasound gels listed above conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and EC Council Directive 2007/47/EC dated 5 September 2007 and it is in accordance with EN ISO 9001:2008, as implemented by the European Union's Medical Devices Regulations.

Ultragel Hungary 2000 Kft. agrees to develop, implement and maintain a formally-recognised EN ISO 9001:2008 and EN ISO 13485:2016 Quality Management System to ensure continued adequacy and efficacy. It also harmonizes with standards EN 14971:2013, EN 15223-1:2017, EN 10993-1:2010.

Ultragel Hungary 2000 Kft. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Ultragel Hungary 2000 Kft. agrees In EC Council Directive 93/42/EEC dated 14 June 1993 appendix meets the essential requirements and provides capabilities intended by the manufacturer. Under normal conditions will not endanger the patient, the operator or other person in the health and safety.

Ultragel Hungary 2000 Kft. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Signed by the Ultragel Hungary 2000 Kft. designated representative:

Name: Komáromy Balázs Title: Managing director

Date: 21.05.2020

Ultragel Hungary 2000 Kft.

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