

EU Declaration of Conformity

Manufacturer: Ultragel Hungary 2000 Kft.

Manufacturer's Address: HU 1023 Budapest, Bécsi út 4.

Single registration number (SRN): SRN HU-MF-000007656

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Device/s: Ultrasound gels :

AquaUltra Basic

AquaUltra Clear

AquaUltra Aloe

HYPERSCAN100

Aqua-LUB

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

and the above mentioned medical devices, are professionally used diagnostic and therapeutic medical device (s), which function as a medium for conducting ultrasound signals in ultrasound examinations and thus contribute to better imaging.

Manufacturer's product group: Basic-UDI-DI gels = 5996627USGEL

Declaration of Conformity

Ultragel Hungary 2000 Kft. declares that ultrasound gels listed above conform to the relevant provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 .

Ultragel Hungary 2000 Kft. agrees to develop, implement, maintain and certification procedure the MSZ EN ISO 13485:2016 Quality Management System to ensure continued adequacy and efficacy.

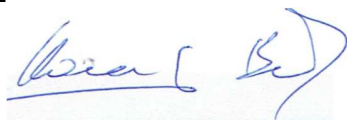
Ultragel Hungary 2000 Kft. confirms that no medicinal products/drugs, tissues or cells of human or animal origin and blood derivative are incorporated in any devices covered by the Device Schedule.

Ultragel Hungary 2000 Kft. agrees In Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 meets Annex 1 the General safety and performance 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.

Signed by the Ultragel Hungary 2000 Kft. designated representative:

Name: Komáromy Balázs Title: Managing director

Date: 01.04.2021 V2



Ultragel Hungary 2000 Kft.

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