

ULTRASOUND GELS

MANUFACTURER'S STATEMENT

Name of Manufacturer: Ultragel Hungary 2000 Kft.

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

I hereby declare that in respect to the following products:

<u>ULTRASOUND GELS</u> (AQUAULTRA BASIC, AQUAULTRA CLEAR, AQUAULTRA ALOE, HYPERSCAN 100, AQUA-LUB)

manufactured by Ultragel Hungary 2000 Kft.

- 1. The raw materials used during the manufacturing process do not contain medicines, human blood derivatives and tissues of animal origin. Do not contain asbestos and free from Butadiene and Heavy Metals.
- Quality controlled row materials are used for the manufacturing of gels produced by Ultragel Hungary 2000 Kft. The quality of the produced gel continuously is checked by inner and outside lab.
 The used raw materials have Biocompatibility tests according to Cytotoxicity (IEC / ISO 10993-5) Irritation / Intracutaneous Reactivity (IEC / ISO10993-10) & Sensitization (IEC / ISO10993-10)) or Ph.Eur.8.0. quality.

During the applied process irritation and allergic reactions caused by the gels produced are not expected, only negligible chance of such reactions . 20.10.2020 Budapest

Mr. Balázs Komáromy Managing director (CEO) Ultragel Hungary 2000 Kft.

Vousioner bally