EU Declaration of Conformity
for distributor Diagramm Halbach GmbH & Co. KG

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:

Aquaultra Clear Ultrasound gels	item No.	UC260	meets	Clinical® Ultrasound gel	item No.	848451
Aquaultra Clear Ultrasound gels	item No	UC500		Clinical® Ultrasound gel	item No	848471
Aquaultra Clear Ultrasound gels	item No	UC1000		Clinical® Ultrasound gel	item No.	848441
Aquaultra Clear Ultrasound gels	item No	UCU5000		Clinical® Ultrasound gel	item No	848460
Aquaultra Clear Ultrasound gels	item No	UCK5000		Clinical® Ultrasound gel	item No.	848461
Aquaultra Basic Ultrasound gels,	item No.	UB260		Clinical® Ultrasound gel Blue	item No	848500
Aquaultra Clear Ultrasound gels	item No	UBU5000		Clinical® Ultrasound gel Blue	item No	848502
Conti gel ECG gel	item No,	GP260		Clinical® Electrode gel	item No.	848355
Conti Spray ECG spray	item No.	ES250		Clinical® Electrode spray	item No.	848333
Conti Spray ECG spray	item No.	ESK5000		Clinical® Electrode spray	item No.	848334

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

and the above mentioned Ultrasound gels 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 =5996627USGEL

and the above mentioned ECG gels and spray medical devices are professionally used diagnostic and therapeutic medical device (s) that reduce resistance between the skin and the test device.
Manufacturer's product group: Basic-UDI-DI = 5996627ECGGEL

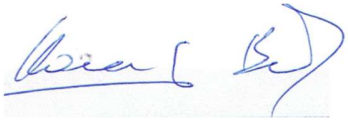
Declaration of Conformity
Ultragel Hungary 2000 Kft. declares that ECG gels listed above conform to the relevant provisions of the Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 .

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



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