EU Declaration of Conformity for distributor Medplus s.r.o.

Manufacturer: Ultragel Hungary 2000 Kft.
Manufacturer's Address: HU 1022 Budapest, Aranka utca 12.
Single registration number (SRN): SRN HU-MF-000024473
This declaration of conformity is issued under the sole responsibility of the manufacturer

Device/s:

AquaUltra Clear Ultrasound gel item No.UC260 meets
AquaUltra Clear gel pro ultrasonografii item No.UC260
AquaUltra Clear Ultrasound gel item No.UC500 meets
AquaUltra Clear gel pro ultrasonografii item No.UC500
AquaUltra Clear Ultrasound gel item No.UC1000 meets
AquaUltra Clear gel pro ultrasonografii item No.UC1000
AquaUltra Clear Ultrasound gel item No.UCU5000 meets
AquaUltra Clear gel pro ultrasonografii item No.UCU5000
AquaUltra Clear Ultrasound gel item No.UCK5000 meets
AquaUltra Clear gel pro ultrasonografii item No. UCK5000
Hot & Cold pack item No.13,5x28cm meets Hot & Cold Sácek item No.13,5x28cm

AquaLaser IPL&Laser gel	item No.UI260	meets	AquaLaser IPL&Laser gel item No.UI260
AquaLaser IPL&Laser gel	item No.UI260pp	meets	AquaLaser IPL&Laser gel item No.UI260pp
AquaLaser IPL&Laser gel	item No.UI500	meets	AquaLaser IPL&Laser gel item No.UI500
AquaLaser IPL&Laser gel	item No.UI1000	meets	AquaLaser IPL&Laser gel item No.UI1000
AquaLaser IPL&Laser gel	item No.UIK5000	meets	AquaLaser IPL&Laser gel item No.UIK5000

EC Product Class: Class I in accordance with Annex VIII, Rule 1.and the above mentioned Ultrasound gel 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= 5996649USGEL

and the above mentioned Hot&Cold pack medical devices are professionally and consumer used hot and cold retainer therapeutic medical device.
Manufacturer's product group: Basic-UDI-DI= 5996649HOTCOLDGEL

and the above mentioned IPL&Laser gelmedical devices are professionally used diagnostic and therapeutic medical device (s) that reduce resistance between the skin and the test device, improve the effectiveness of physiotherapy treatments.
Manufacturer's product group: Basic-UDI-DI = 5996649IPLGEL

Declaration of Conformity

Ultragel Medical Kft. declares that 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 Medical 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 Medical 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 Medical 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 Medical Kft. designated representative:
Name: Szakmáry Laura
Title: Managing director

Date: 02.05.2022 V01

Ultragel Medical Kft.
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