



## EU Declaration of Conformity

**Manufacturer:** Ultragel Medical Kft.

**Manufacturer's address:** 1022 Budapest, Aranka utca 12.

Single registration number (SRN):

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

**Device/s:** Hot & Cold pack Hot/Cold retainer gel pack

EC Product Class: Class I in accordance with Annex VIII, Rule 1. and the above mentioned medical devices are professionally and consumer used hot and cold retainer therapeutic medical device.

**Manufacturer's product group:** Basic-UDI-DI = 5996649HOTCOLDGEL

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### Declaration of Conformity

Ultragel Medical Kft. declares that gel 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 V1

A handwritten signature in blue ink, appearing to be 'Szakmáry Laura', written over a light blue horizontal line.