EC Declaration of Conformity

EC Declaration of Conformity Class I devices to Medical Devices Directive 93/42/EEC

Manufacturer: ULTRAGEL HUNGARY 2000 Kft.
Manufacturer's Address: HU 1023 Budapest, Bécsi út 4.
Device/s: Disposable and reuseble ECG electrodes
EC Product Class: Class I in accordance with Annex IX, Rule 1.

Declaration of Conformity
ULTRAGEL HUNGARY 2000 Kft. declares that Disposable and reuseble ECG electrodes conform to the relevant provisions of the EC Council Directive 93/42/EEC dated 14 June 1993 and EC Council Directive 2007/47/EC dated 5 September 2007 and it is in accordance with EN ISO 9001:2008, as implemented by the European Union's Medical Devices Regulations.

ULTRAGEL HUNGARY 2000 Kft. agrees to develop, implement and maintain a formally-recognised EN ISO 9001:2008 Quality Management System to ensure continued adequacy and efficacy.

ULTRAGEL HUNGARY ngary 2000 Kft. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

ULTRAGEL HUNGARY 2000 Kft. agrees In EC Council Directive 93/42/EEC dated 14 June 1993 appendix meets the essential 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.

ULTRAGEL HUNGARY 2000 Kft. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Signed by the ULTRAGEL HUNGARY 2000 Kft. designated representative:

Name: __Komáromy Balázs_____ Title: Managing director

Date: 06.10.2017

Digitally signed by Potînga Stela
Date: 2023.02.10 10:16:48 EET
Reason: MoldSign Signature
Location: Moldova

Ultragel Hungary 2000 Kft.

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