GELLO® GmbH Geltechnik · Harmate 28 · D-48683 Ahaus-Wüllen

EU Declaration of Conformity

according to Annex IV of Regulation 2017/745

We

Gello GmbH Geltechnik, Harmate 28; D-48683 Ahaus, Germany
SRN DE-MF-000010607 (SRN according to Article 31)

declare on our own responsibility that the product,

Ultrasonic Gel
Base UDI-DI: 42517651AG40AG45YJ

complies with Regulation 2017/745 and the relevant Union legislation.

As coding standard has been selected the issuing entity GS1, in accordance with Article 27(2) or Article 120 (12).

Non-sterile ultrasound gel is a non-invasive medical device in accordance with REGULATION (EU) 2017/745, Annex VIII, Chapter III, paragraph 4f, Regulation 1, and belongs to Class I.

Ultrasound gel is intended as a contact agent for the external use of ultrasound devices and can be used in therapeutic and diagnostic medicine. The product is applied by qualified personnel.

The GENERAL SAFETY AND PERFORMANCE REQUIREMENTS are in conformity with Regulation (EU) 2017/745 Annex I and they are part of the Technical Documentation referred to in Annex II of EU Regulation 2017/745.

The applied standards are recorded in FB 3.2-1 "List of higher-level documents" and considered in the context of the conformity assessment procedure. The update takes place at least annually as part of risk management.

No notified body is required for devices in risk class I, so there is no description of the conformity assessment procedure and no indication of the name and identification number of the notified body.

Ahaus, 19.02.2026

Klaus Roters BdoL, QM,
Gello GmbH Geltechnik