SONOGEL® vertriebs GMBH

SONOGEL Vertriebs GmbH · Otto-Hahn-Str. 15A · 65520 Bad Camberg

Otto-Hahn-Straße 15A
65520 Bad Camberg
Telefon 0 64 34 / 3 74 21
Telefax 0 64 34 / 3 74 24
www.sonogel.de
info@sonogel.de

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002

This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian ***Therapeutic Goods (Medical Devices) Regulations 2002*** relating to the devices stated below.

Manufacturer's Name: Sonogel Vertriebs GmbH

Business Address: Otto-Hahn-Straße 15A, 65520 Bad Camberg, Germany

Medical Devices: SONOGEL Contact Gel

Classification: Class 1

GMDN Code and Term: 15321 - Gel, ultrasonic coupling

Scope of Application: All lots

For ach kind of medical device to which the technical documentation applies, the devices comply with the declaration of conformity procedures the applicable provisions of the essential principles and the classification rules before being supplied.

Standards Applied: **DIN ISO 13485:2016** Medical Devices – Quality Management Systems – Requirements for regulatory purposes.
DIN ISO 14971:2012 Medical devices – Risk management for medical devices.

Authorised Signatory:

Frank Linde, Managing Director

20.01.2021
Date

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Amtsgericht Limburg HRB 1132
Geschäftsführer: Frank Linde
Ust-Id-Nr. DE113877897
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