EU DECLARATION OF CONFORMITY

Manufacturer:	Richter Rubber Technology Sdn. Bhd. Plot 209, Kuala Ketil Industrial Estate, 09300 Kuala Ketil, Kedah Darul Aman, Malaysia. Fax.: +60 4 4161667 Tel.: +60 4 4161668 / 9 e-Mail: richter@myrrt.de Website: www.myrrt.de SRN: MY-MF-000023324
Product:	Natural Latex Probe Cover Brand: Heinz Herenz Sonosafe Probe Cover
Intended purpose:	Intended for barrier protection during invasive medical examination and diagnosis using a transducer probe
Classification:	Class IIa device in accordance with Rule 5 of Annex V
Standards used:	ISO 13485:2016, ISO 4074:2015, ISO 10993-1:2009, ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 14971:2019

We, Richter Rubber Technology Sdn Bhd declare that the stated products are in conformity with the essential requirements and provision of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC. It is subjected to the procedure set out in Annex V of Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC related to medical devices and meets the essential health and safety requirements

Notified body:	SGS Belgium NV, SGS House Noorderlaan 87 2030 Antwerp Belgium
Notified Body No.:	CE 1639
Certification No.:	MY19/1811030223 valid from 04 March 2020 until 30 April 2024
European Representative:	Nils Gerber rrt Vertrieb Und Service GmbH Heinrich-Kümmel Str.3, 30169 Hannover Tel: +49- 1709007723 Email: nils@myrrt.de SRN: DE-AR-000021443
Place of Declaration:	Richter Rubber Technology Sdn Bhd, Malaysia
Signature:	 Name: Fabian Knauthe Position: Managing Director
Date:	07.07.2022

EC Certificate Production Quality Assurance System: Certificate MY19/1811030223

The management system of

Richter Rubber Technology Sdn. Bhd.

Plot 209 & 214, Kuala Ketil Industrial Estate
09300 Kuala Ketil, Kedah
MALAYSIA

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex V

For the following products

Packaged Water Based Warming & Cooling Lubricant intended for Management of Atrophic Vaginitis.
Non Sterile Natural Latex Probe Cover intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 04 March 2020 until 30 April 2024
and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 24 July 2000
and first certified by SGS Belgium NV since 16 December 2019

Certification is based on reports numbered MY/KUL/ MY00325

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

LPMD5008 - Certificate CE1639 AnnexV_EN rev. 01