

**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](mailto:richter@myrrt.de)  
Website: [www.myrrt.de](http://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](mailto: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 Noordertaan 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

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