

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: Non-Medicated Natural Latex Condoms
Brands: EXS Ribbed and Dotted, EXS Regular Comfy Fit, EXS Mixed Flavoured, EXS Chocolate, EXS Strawberry, EXS Bubble Gum, EXS Cola, EXS Glow in the dark / Glowing, EXS Extra Thick, EXS Snug Fit, EXS Black Latex, EXS Nano Thin, EXS Magnum, EXS Jumbo, EXS Warming, EXS Cooling, EXS Pure

Intended purpose: Used for contraceptives and for prophylactic purposes (to help prevent pregnancy and the transmission of sexually transmitted infections (STIs)).

Classification: Class IIb device in accordance with Rule 14 of Annex IX of Medical Device Directive 93/42/EEC

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 II and Annex VII of Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC related to medical devices.

Notified body: SGS Belgium NV,
SGS House Noorderlaan 87 2030 Antwerp Belgium

Notified Body No.: CE 1639

Certification No.: MY19/1811030226 valid from 16 December 2019 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: 26.04.2023