



KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS	Doc. No. K-DOC – 075	
		Issue No. 00	
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European Communities Council Directive 93/42/EEC Concerning Medical Devices. (including the revisions from Directive 2007/47/EC.)

This declaration of conformity is issued under the sole responsibility of Karex Industries Sdn. Bhd.

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name: Non-sterile Non-medicated Natural Rubber Latex Male Condoms

Manufacturer: Karex Industries Sdn. Bhd.
PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.

Trade Name: As shown in Appendix 1

Intended Use: For contraception and prevention of sexually transmitted infections.

Standards tested to: ISO 4074:2015, EN ISO 4074:2015

MDD Directive Classification No: Class IIb, Rule 14

GMDN Code: 45138 (Basic Male Condom, Hevea Latex)

Notified Body: TUV SUD Product Service GmbH (0123)
Zertifizierstelle Ridlerstraße 65, 80339 MÜNCHEN, Germany

EU Authorised Representative: Advena Ltd.
Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

Medical Device Directive Assessment route: Annex II (excluding section 4)

EC Certificate Number: G1 102558 0002 Rev.01

Signed


Tee Poh Suan
Senior Group RA Manager
Port Klang, Selangor, Malaysia



Date

31st May 2021

Who is the legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under the name of Karex Industries Sdn. Bhd. regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.



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Appendix I

Brand Name	Sub-brand	Product Code	Colour	Flavours
Mister Size	47	P47S XUT	Natural	Non-flavoured
Mister Size	49	O77 XUT	Natural	Non-flavoured
Mister Size	53	P53S XUT	Natural	Non-flavoured
Mister Size	57	D17 XUT	Natural	Non-flavoured
Mister Size	60	Z21 XUT	Natural	Non-flavoured
Mister Size	64	U22 XUT	Natural	Non-flavoured
Mister Size	69	U31 XUT	Natural	Non-flavoured