



KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS	Doc. No. K-DOC-001	
		Issue No. 22	
Date	14 th April 2021	Page	1 of 14

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 Annex I – Product Listing

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

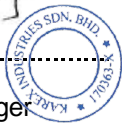
EU Authorised Representative: Advena Ltd.
Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.

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

EC Certificate Number: G1 102558 0002

Signed


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



Date

14.04.2021

Who is the legal person with responsibility for the design, manufacture, packaging and labelling the device that 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.



KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS	Doc. No. K-DOC-001	
		Issue No. 22	
Date	30 th October 2024	Page	1 of 2

Karex Industries Sdn. Bhd.

PTD 7906 & 7907, Taman Pontian Jaya, Batu 34 Jalan Johor, 82000 Pontian, Johor, Malaysia.

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit the Manufacturer from issuing a new Declaration of Conformity or amending, modifying, or supplementing any existing MDD Declaration of Conformity from 26th May 2021.

We, hereby confirm that the change(s) detailed in the table below do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG-2020-3(4). The related Declaration of Conformity remains valid until the end of the transitional period of MDD.

Appendix 12 to K-DOC-001: *Non-significant changes after the 26th May 2021 as per the Transitional Provisions of MDR Article 120(3).*

Annex I – Product Listing

Brand Name	Sub-brand	Barcode	CS Number
Mister Size	47	4260605480010	K-CS-167-01
		4260605482281	K-CS-167-35
		4260605480027	K-CS-167-08
		4260605480034	K-CS-167-15
Mister Size	49	4260605480058	K-CS-167-09
		4260605482298	K-CS-167-36
		4260605480041	K-CS-167-02
		4260605480065	K-CS-167-16
Mister Size	53	4260605482304	K-CS-167-37
		4260605480072	K-CS-167-03
		4260605480089	K-CS-167-10
		4260605480096	K-CS-167-17
Mister Size	57	4260605480126	K-CS-167-18
		4260605480119	K-CS-167-11
		4260605482168	K-CS-167-38
		4260605480102	K-CS-167-04
Mister Size	60	4260605482175	K-CS-167-39
		4260605480140	K-CS-167-12
		4260605480157	K-CS-167-19
		4260605480133	K-CS-167-05



KAREX INDUSTRIES SDN. BHD.

Title	DECLARATION OF CONFORMITY FOR NON-STERILE NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS	Doc. No. K-DOC-001	
		Issue No. 22	
Date	30 th October 2024	Page	2 of 2

Mister Size	64	4260605480171	K-CS-167-13
		4260605482182	K-CS-167-40
		4260605480188	K-CS-167-20
		4260605480164	K-CS-167-06
Mister Size	69	4260605482199	K-CS-167-41
		4260605480201	K-CS-167-14
		4260605480218	K-CS-167-21
		4260605480195	K-CS-167-07
Mister Size	Sample Pack 47-49-53	4260605480577	K-CS-167-30
Mister Size	Sample Pack 53-57-60	4260605480584	K-CS-167-42
Mister Size	Sample Pack 60-64-69	4260605481178	K-CS-167-29
Mister Size	Test-Set 53-57-60 with measuring tape	4260605481987	K-CS-167-23

Signed

Khairunnisa Warsito
Group RA Manager
Port Klang, Selangor, Malaysia



Date 30.10.2024