

Title	DECLARATION OF CONFORMITY FOR NON-STERILE, NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS	Doc. No. M-DOC-02
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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 Medical-Latex (DUA) 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: Medical – Latex (DUA) SDN. BHD.
PLO 8, Senai Industrial Estate,
81400, Senai, Johor,
Malaysia

Trade Name:

Brand	Distributor
Pasante	Pasante Healthcare Ltd

Intended Use: For contraceptive and prophylactic purposes to help prevent pregnancy and transmission of sexually transmitted infections.

Standards tested to: ISO 4074:2015(E)

MDD Directive Classification No: Class IIb, Rule 14

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

Notified Body: BSI Netherlands

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

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

EC Certificate Number: CE 664546



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Tee



Signed

Date : 21st October 2021

Name: Tee Poh Suan

Designation: Senior Group RA Manager

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 Medical – Latex (DUA) 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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Annex 1 – Product Listing

	Type	Shape and texture	Color	Lubricant	Flavor
1	49mm Small	Parallel and Smooth	Natural	Silicone	None
2	52mm Superthin	Parallel and Smooth	Natural	Silicone	None
9	52mm Regular Yellow	Parallel and Smooth	Yellow	Silicone	Orange
12	52mm Retarding (Extra Thick)	Parallel and Smooth	Natural	Silicone	None
13	52mm Ribbed	Parallel and Ribbed	Natural	Silicone	None
14	52mm Ribbed	Parallel and Ribbed	Natural	Silicone	Warming Lubricant
15	52mm Ribbed	Parallel and Ribbed	Natural	Silicone	Cooling (Peppermint)
18	52mm G-Pleasure	Big Head, ribbed and dotted	Natural	Silicone	None
20	52mm Extra Superthin	Parallel and Smooth	Natural	Silicone	None
24	56mm Large big head Black	Big Head and Smooth	Black	Silicone	None
37	60mm XL Regular	Parallel and smooth	Natural	Silicone	None
38	69mm XXL Regular	Parallel and smooth	Natural	Silicone	None
39	53mm Regular Red	Parallel and Smooth	Red	Silicone	Strawberry
40	53mm Regular Green	Parallel and Smooth	Green	Silicone	Mint
41	53mm Regular Blue	Parallel and Smooth	Blue	Silicone	Blueberry/Bubblegum
42	53mm Regular Brown	Parallel and Smooth	Brown	Silicone	Chocolate/Cola
43	53mm Regular Yellow	Parallel and Smooth	Yellow	Silicone	Banana/Pineapple
44	53mm Regular Orange	Parallel and Smooth	Orange	Silicone	Mango
45	53mm Regular	Parallel and Smooth	Natural	Silicone	Coconut
46	53mm Regular Red	Parallel and Smooth	Red	Silicone	None
49	54mm Big Head Naturelle	Big Head and smooth	Natural	Silicone	None