



<b>Title</b>	<b>DECLARATION OF CONFORMITY FOR NON-STERILE, NON-MEDICATED NATURAL RUBBER LATEX MALE CONDOMS</b>	<b>Doc. No. M-DOC-02</b>
		<b>Revision 0</b>
<b>Date</b>	<b>21<sup>st</sup> October 2021</b>	<b>Page 1 of 3</b>

**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

<b>Trade Name:</b>	<b>Brand</b>	<b>Distributor</b>
	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**