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**