



EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)

(Devices in Class IIa, IIb or III)

No. G1 102558 0002 Rev. 01

Manufacturer:

Karex Industries Sdn. Bhd.

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

Product Category(ies):

Non-Sterile Non-Medicated Natural Rubber Latex Male Condoms intended for Contraception and Prevention of Sexually transmitted Infections; Non-Sterile, Non-Medicated Natural Rubber Latex Male Condoms with Applicator intended for Contraception and Prevention of Sexually transmitted Infections

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11025580002Rev.01

Report No.:

MYQMH0820030-721425864

Valid from:

2020-10-19

Valid until:

2024-05-26

Date,

2020-10-19

Christoph Dicks
Head of Certification/Notified Body