ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

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:G1 102558 0002 Rev. 01

Report No.: MYQMH0820030-721425864

Valid from: 2020-10-19
Valid until: 2024-05-26

Certificate: CE
Product group: M05
Date of issue: 19-10-20
Mfg no: 577272
Exp: 26-05-24
Pages: 1

Digitally signed by Approved by Omkar Dhuri IDA Quality Affairs
Date: 2021.12.28 19:01:26 +05'30'

Date, 2020-10-19

Christoph Dicks
Head of Certification/Notified Body

Digitally signed by Granaci Boris
Date: 2024.04.22 16:21:55 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany