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
BS-MDR-099

Certificate: CE
Product group: M05
Date of issue: 03-08-23
Mfg no: 577272
Exp: 02-08-28
Pages: 2

Seemran Sawant
Digitally signed by Seemran Sawant
Date: 2024.10.31 11:38:54 +05'30'

TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 102558 0008 Rev. 00

Manufacturer:

Karex Industries Sdn. Bhd.
PTD 7906 & 7907
Taman Pontian Jaya
Batu 34 Jalan Johor
82000 Pontian, Johor
MALAYSIA

SRN Manufacturer - MY-MF-000001247

Authorized Representative:

Advena Limited
Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013, MALTA

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 102558 0008 Rev. 00

Report No.: MYQMH0121061-721427127

Valid from: 2023-08-03
Valid until: 2028-08-02

Digitally signed by Granaci Boris
Date: 2025.06.02 09:29:58 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-08-03

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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(Class IIa and Class IIb Devices)

No. G10 102558 0008 Rev. 00

Classification:	Class IIa
Device Group:	Z11040185 - ULTRASOUND SCANNERS - CONSUMABLES
Intended Purpose:	-

Classification:	Class IIb
Device Group:	U110101 - CONDOMS
Intended Purpose:	For contraception and prevention of sexually transmitted infections

Classification:	Class IIb
Device Group:	U110299 - DEVICES FOR FEMALE CONTRACEPTION - OTHER
Intended Purpose:	To be used as a barrier when performing oral-vaginal sex or oral-anal sex to help reduce the risk of sexually transmitted infections (STIs)

The validity of this certificate depends on conditions and/or is limited to the following: -

Revision History:

Rev.	Dated	Report	Description
00	2023-08-03	MYQMH0121061-721427127	Initial issuance

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