





Certificate

No. Q5 102558 0001 Rev. 02

Holder of Certificate: Karex Industries Sdn. Bhd.

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

Certification Mark:



Scope of Certificate: Design and Development and Manufacture of Non-

sterile Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Nonsterile Warming, Cooling, Plain Water Based Lubricant Jelly, Sterile and Non-sterile Natural Rubber Latex Protective Transducer Covers, Sterile and Non-sterile Non-Latex Protective Transducer Covers

Manufacture of Non-sterile Silicone Oil Based Lubricant to Treat Vaginal Dryness

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 102558 0001 Rev. 02

Report No.: 5585260-721429352

 Valid from:
 2022-07-04

 Valid until:
 2025-07-02

Certificate: IS Product group: M05 Date of issue: 04-07-22 Mfg no: 577272 Exp: 02-07-25 Pages: 2 Digitally signed by Approved by Omkar Dhuri, Documentation Officer, Quality Affairs, IDA Date: 2023.01.06 21:18:32 +05'30'

Date, 2022-07-04

Christoph Dicks

Head of Certification/Notified Body





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EN ISO 13485:2016 Applied Standard(s):

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Karex Industries Sdn. Bhd. Facility(ies):

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

82000 Pontian, Johor, MALAYSIA

Manufacture of Non-sterile Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Warming, Cooling, Plain Water Based Lubricant Jelly, Sterile and Non-sterile Natural Rubber Latex Protective Transducer Covers, Sterile and Nonsterile Non-Latex Protective Transducer Covers, Non-sterile Silicone Oil Based Lubricant

Karex Industries Sdn. Bhd.

Lot 2244, Batu 39 1/2 Pontian Besar, 82000 Pontian, Johor,

MALAYSIA

Design and Development and Manufacture of Non-sterile Nonmedicated Natural Rubber Latex Male Condom, Non-sterile Nonmedicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Warming, Cooling, Plain Water Based Lubricant Jelly, Sterile and Non-sterile Natural Rubber Latex Protective

Transducer Covers, Sterile and Non-sterile Non-Latex Protective

Transducer Covers

Manufacture of Non-sterile Silicone Oil Based Lubricant to Treat

Vaginal Dryness

Karex Industries Sdn. Bhd.

Lot 7747, Batu 32, Jalan Pontian Johor, 82000 Pontian, Johor, MALAYSIA

Warehousing of Non-sterile Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Warming, Cooling, Plain Water Based Lubricant Jelly, Sterile and Non-sterile Natural Rubber Latex Protective Transducer Covers, Sterile and Nonsterile Non-Latex Protective Transducer Covers, Non-sterile Silicone Oil Based Lubricant to Treat Vaginal Dryness and Nonsterile Silicone Oil based Lubricant to treat vaginal dryness

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