



Product Service

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, 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

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

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Valid until: 2025-07-02

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Product group: M05
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by Approved by
Omkar Dhuri,
Documentation
Officer, Quality
Affairs, IDA
Date: 2023.01.06
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Date, 2022-07-04

Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 102558 0001 Rev. 02

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Karex Industries Sdn. Bhd.
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 Non-
sterile 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 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 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 Non-
sterile Non-Latex Protective Transducer Covers, Non-sterile
Silicone Oil Based Lubricant to Treat Vaginal Dryness and Non-
sterile Silicone Oil based Lubricant to treat vaginal dryness