



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 102558 0001 Rev. 04

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 Non-latex Male condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Natural Rubber Latex Prophylactic Dam, 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, Certification, Validation and Verification Regulations 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. 04

Report No.: 721435539

Valid from: 2025-07-03
Valid until: 2028-07-02

Date, 2025-03-10

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes



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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 Non-latex Male condom, Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Natural Rubber Latex Prophylactic Dam, 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 Non-medicated Non-latex Male condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom, Non-sterile Non-medicated Natural Rubber Latex Male Condom with Applicator, Non-sterile Natural Rubber Latex Prophylactic Dam, 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

Karex Industries Sdn. Bhd.

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

Warehousing of Non-sterile Non-medicated Non-latex Male condom, 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, Non-sterile Non-latex Protective Transducer Covers, Non-sterile Natural Rubber Latex Prophylactic Dam and Non-sterile Silicone Oil Based Lubricant