

SGS

Certificate MY99/51085

The management system of

Karex Industries Sdn. Bhd.

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

has been assessed and certified as meeting the requirements of

ISO 13485:2003 EN ISO 13485:2012

For the following activities

Design & Manufacture of Non-Sterile Non-Medicated Natural Rubber Latex Male Condoms Intended for Contraception and Prevention of Sexually Transmitted Infections, Non-sterile Warming, Cooling and Regular Plain Water based Lubricant Jelly Intended to treat Vaginal Dryness and Non-sterile Natural Rubber Latex & Non-Latex Protective Transducer Covers Intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.

Design & Manufacture of Non-Sterile Non-Medicated Natural Rubber Latex Male Condoms with Applicator intended for Contraception and Prevention of Sexually Transmitted Infections.

Design & Manufacture of Non-Sterile Non-Medicated Non-Latex Male Condoms Intended for Contraception and Prevention of Sexually Transmitted Infections.

This certificate is valid from 28 September 2016 until 31 March 2019 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 31 March 2019
Issue 14. Certified since 19 November 1999

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by



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Karex Industries Sdn. Bhd.

ISO 13485:2003
EN ISO 13485:2012



Issue 14

Detailed scope

Design & Manufacture of Non-Sterile Non-Medicated Natural Rubber Latex Male Condoms Intended for Contraception and Prevention of Sexually Transmitted Infections, Non-sterile Warming, Cooling and Regular Plain Water based Lubricant Jelly Intended to treat Vaginal Dryness and Non-sterile Natural Rubber Latex & Non-Latex Protective Transducer Covers Intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.

Design & Manufacture of Non-Sterile Non-Medicated Natural Rubber Latex Male Condoms with Applicator intended for Contraception and Prevention of Sexually Transmitted Infections.

Design & Manufacture of Non-Sterile Non-Medicated Non-Latex Male Condoms Intended for Contraception and Prevention of Sexually Transmitted Infections.

Additional facilities

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

MOHD YACOB KARIM
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SELANGOR
MALAYSIA

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14 SEP 2016

This is to certify that the signature appears on this document/Certificate/Marriage Certificate/Birth/Death Certificate is that of **MOHD YACOB KARIM** who is **Notary Public**.....
The Ministry of Foreign Affairs, Malaysia is not responsible of the accuracy of the information contained therein.



TAN SENG KHEE
Consular Officer
Consular Division
Ministry of Foreign Affairs
Putrajaya Malaysia

14 SEP 2016

Karex Industries Sdn. Bhd.

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 10

Detailed scope

Non-medicated Natural Rubber Latex Male Condoms

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

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



EC Certificate Full Quality Assurance System: MY99/51084



The management system of

Karex Industries Sdn. Bhd.

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Non-medicated Natural Rubber Latex Male Condoms

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

This certificate is valid from 28 September 2013 until 28 September 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 28 July 2016
Issue 10. Certified since 19 November 1999

Certification is based on reports numbered **MY00366**

This is a multi-site certification

Additional site details are listed on the subsequent page

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

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