EC Certificate Production Quality Assurance System: Certificate MY99/00528

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 V

For the following products

Non-Sterile Natural Rubber Latex Protective Transducer Cover Intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.
Non-Sterile Warming, Cooling and Regular Plain Water based Lubricant Jelly intended to treat Vaginal Dryness.
Non Sterile, Non Latex Protective Transducer Cover Intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 28 September 2016 until 28 September 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 28 July 2019
Issue 13. Certified since 19 November 1999

Certification is based on reports numbered MY/KUL MY00336

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

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311 M2

Karex Industries Sdn. Bhd.

Directive 93/42/EEC

on medical devices, Annex V

Issue 13

Detailed scope

Non-Sterile Natural Rubber Latex Protective Transducer Cover Intended for Barrier Protection during Invasive Medical Examination and Diagnosis using Transducer Probe.
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Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

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