

EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

No. CE 664546
Issued To: **Medical-Latex (DUA) SDN BHD**
Plo 8 Senai Industrial Estate
Senai
Johor
81400
Malaysia

In respect of:

The design, development and manufacture of natural rubber latex lubricated, flavoured and coloured condoms.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 0086):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **21 November 2016**

Date: **21 November 2016**

Expiry Date: **25 April 2018**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:

Service(s) supplied

Advena Limited
Tower Business Centre
2nd Floor, Tower Street
Swata
BKR 4013
Malta

EU Representative

Karex Industries Sdn Bhd
PTD 7906 & 7907
Taman Pontian Jaya
Batu 34, Jalan Johor
Pontian, Johor
82000
Malaysia

Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

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Date	Reference Number	Action
21 November 2016	8644964	First issue. Transferred from Another Notified Body.

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