By Royal Charter

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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EC Certificate - Full Quality Assurance System

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

List of Significant Subcontractors

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

Certificate No:	**CE 664546**
Date:	**21 November 2016**
Issued To:	**Medical-Latex (DUA) SDN BHD** **Plo 8 Senai Industrial Estate** **Senai** **Johor** **81400** **Malaysia**

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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