

EC Certificate - Full Quality Assurance System

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

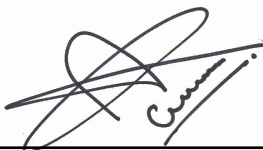
No. **CE 618361**
Issued To: **Eurolatex Sdn. Bhd.**
Plot 33 Kuala Ketil Industrial Estate
09300 Kuala Ketil
Kedah
Malaysia

In respect of:

Design, development and manufacture of non-medicated natural rubber latex condom and latex probe cover.

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 2797):



Albert Roossien, Regulatory Lead

First Issued: **2016-02-19**

Date: **2019-03-04**

Expiry Date: **2021-02-18**

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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.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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List of Significant Subcontractors

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

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09300 Kuala Ketil
Kedah
Malaysia

Subcontractor:

Service(s) supplied

CIRIANO GLOBAL S.L.
C/Blancas 4-6, 1 B
Zaragoza
50001
Spain

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 618361**
 Date: **2019-03-04**
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09300 Kuala Ketil
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Date	Reference Number	Action
19 February 2016	8196823	First issue.
Current	9739799	Traceable to NB 0086.

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