

EC Certificate - Full Quality Assurance System

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

No. [REDACTED]
Issued To: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

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):

Stewart Brain, Head of Compliance & Risk -
Medical Devices

First Issued: 2016-11-21

Date: 2018-07-06

Expiry Date: 2023-04-25

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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:

Certificate No: [REDACTED]
Date: **2018-07-06**
Issued To: [REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

Subcontractor:	Service(s) supplied
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	EU Representative
[REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED] [REDACTED]	Manufacture

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: [REDACTED]
 Date: **2018-07-06**
 Issued To: [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]
 [REDACTED]

Date	Reference Number	Action
21 November 2016	[REDACTED]	First issue. Transferred from Another Notified Body.
Current	[REDACTED]	Certificate Renewal

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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.