

EC Certificate Full Quality Assurance System: Certificate MY19/1811030190

The management system of

Nulatex Sdn. Bhd.

Lot 1870, 4th Mile, Jalan Mengkibol
86000 Kluang, Johor
Malaysia

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

**Non-sterile Non-medicated Natural Rubber Latex Male Condoms
intended for Contraception and Prevention
of Sexually Transmitted Infections.**

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 26 March 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 21 October 2010
and first certified by SGS Belgium NV since 26 March 2020

Certification is based on reports numbered MY/KUL MY00937

Authorised by

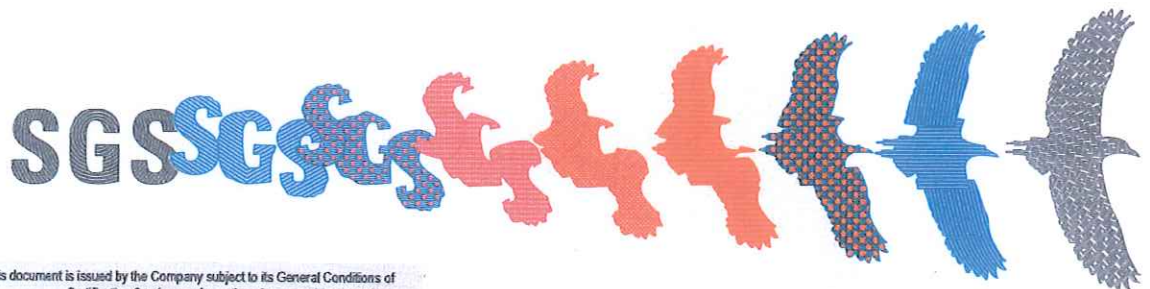


SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Supplementary information to AR120 815990

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to: .

Nulatex Sdn. Bhd.
Lot 1870, 4th Mile, Jalan Mengkibol,
86000 Kluang, Johor
Malaysia

Date: 27 September 2024

Changes Approved:

Date	Reference Number	Action
27 September 2024	30253348	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of device Non-sterile Non-medicated Natural Rubber Latex Male Condoms intended for Contraception and Prevention of Sexually Transmitted Infections. Original NB Certificate Number: MY19/1811030190

27 September 2024

Nulatex Sdn Bhd
Lot 1870, 4th Mile,
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Johor
86000
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To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	BSI Reference Number	Directive and Annex	Reference Number	Changes approved
MY19/1811030190	AR120 815990	93/42/EEC Annex II excluding Section 4	30253348	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of device Non-sterile Non-medicated Natural Rubber Latex Male Condoms intended for Contraception and Prevention of Sexually Transmitted Infections. Original NB Certificate Number: MY19/1811030190

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,



Graeme Tunbridge
Senior Vice President, Medical Devices



05 June 2025

Nulatex Sdn. Bhd.
Lot 1870, 4th Mile,
Jalan Mengkibol,
Kluang
Johor
86000
Malaysia

Our Reference: Supplementary information to AR120 815990

To Mr Ganesh M,

With reference to AR 120 815990 certificate issued by BSI, this letter to confirm that the 93/42/EEC Annex II excluding Section 4 certificate (Certificate Number: MY19/1811030190) remains valid until the end of the transition period as specified in Article 120 (3c) of MDR (as amended by (EU) 2023/607).

Therefore, as stipulated in MDCG 2022-4 Rev.2 clause 1b) guidelines in reference to Article 120 (3c) of MDR (as amended by (EU) 2023/607, the end of transition period (validity) applies to MY19/1811030190 is 31 December 2028, subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Should you have any queries concerning your certification, do not hesitate to contact the Scheme Manager at email address Rohaida.abdmajid@bsigroup.com.

Yours sincerely

Rohaida Majid
Digitally signed
by Rohaida Majid
Date: 2025.06.05
18:15:47 +08'00'

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