EC Certificate Full Quality Assurance System: ID08/01105

The management system of

PT Vonix Latexindo

Jl. Balikpapan No. 21 E, Jakata 10160, Indonesia

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

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 24 March 2014 until 10 December 2018 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 10 December 2018
Issue 11. Certified since 10 December 1998

Certification is based on reports numbered ID290

This is a multi-site certification.
Additional site details are listed on the subsequent page.

Authorised by

SGS United Kingdom Ltd, Notified Body 0120
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SGS CE 01 0311 M2

PT Vonix Latexindo

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 11

Detailed scope

Non-medicated natural latex condoms used for contraception or the prevention of the transmission of sexually transmitted diseases

For placing on the market of Class III devices covered by this certificate, an EC Design Examination Certificate according to Annex II (Section 4) is required.

Additional facilities

Kp. Ledug RT 001/01 KelurahanAlam Jaya, Kecamatan Jati Uwung, Kota Tangerang, Indonesia