EC Certificate Full Quality Assurance System: Certificate GB19/963047



The management system of

Reckitt Benckiser Healthcare (UK) Ltd

Dansom Lane, Hull, HU8 7DS, United Kingdom

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 02 April 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits. Issue 4. Certified since 08 July 1999 and first certified by SGS Belgium NV since 08 April 2019.

> This is a multi-site certification. Additional site details are listed on subsequent pages

> > Certification is based on reports numbered GB/PC 150141

Authorised by



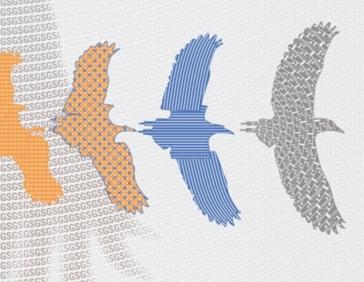
SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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

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Reckitt Benckiser Healthcare (UK) Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4).

Issue 4

Detailed scope

Cryosurgical wart removal devices and kits. Natural rubber latex non-medicated male condoms for contraception and prevention of sexually transmitted infections Synthetic non-medicated male condoms for contraception and prevention of sexually transmitted infections Sterile and non-sterile personal lubricants for alleviation of vaginal dryness Sterile and non-sterile gel medical devices for instrument lubrication, conduction and use in diagnostic examinations. Ingrowing Toenail Treatment (consisting of toenail clips, nail adhesive and cooling spray)

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.

Additional facilities

Reckitt Benckiser also trading as SSL International plc and Qingdao London Durex Co Ltd., No.1-13 Shangma Part, Aodong Road, High-tech Industrial Development Zone, Qingdao City, Shandong Province, P.R. China

> Reckitt Benckiser also trading as SSL Manufacturing (Thailand) Ltd. Wellgrow Industrial Estate 96 & 100, Moo 5, Bangna-Trad Rd, K.M.36, Bangsamak, Bangpakong, Chachoengsao, 24180, Thailand.

Reckitt Benckiser Healthcare Manufacturing (Thailand) Ltd. 65 Moo12 Lardkrabang-Bangplee Rd., Bangplee, Samutprakarn, 10540, Thailand

> Reckitt Benckiser Tatabánya Kft., 2800 Tatabánya, Fatelepi út 15, Hungary



SIGNATURE PAGE

GB19/963047_EC Certificate_Full Quality Assurance_SGS Belgium_All Site **Document Name:**

3.0 Approved CURRENT **Document Version:**

Date (GMT)	Signed by	Reason
20-Apr-2020 14:37:52	Hussey Hannah (HHussey)	Signing as Approver

