EC Certificate Full Quality Assurance System: GB99/50557.01

The management system of

Reckitt Benckiser Healthcare (UK) Ltd

Dansom Lane, Hull, HU8 7DS, UK

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 08 August 2018 until 30 October 2021
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 30 October 2019
Issue 35. Certified since 08 July 1999

Certification is based on reports numbered GB/PC 150141

Multiple certificates have been issued for this scope
The main certificate is numbered GB99/50557.00

Authorised by

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Reckitt Benckiser Healthcare (UK) Ltd

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 35

Detailed scope

- Cryosurgical wart removal devices and kits.
- Natural Rubber Latex Male Contraceptive Condoms with Benzocaine: Durex Pleasuremax; Durex Karşılıklı Zevk; Durex Extended Pleasure; Durex Performa; Durex Mutual Climax; Durex Extended Pleasure óvszer; Durex Settebello Lunga Durata; Durex Mutual Pleasure; Durex Performa Hatù Ritardante; Durex Orgasmic; Durex Placer Prolongado; Durex Performa Intense; Durex Uzayan Zevk; Durex Sync Intended Purpose of Device: Intended as a method of contraception and to prevent the transmission of sexually transmitted infections; benzocaine intended for male genital desensitisation
- 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
- Salicylic acid corn and callous removal plasters; Medical Purpose of Device: for the relief of pressure and removal of corns and callouses
- Sterile and non sterile gel medical devices for instrument lubrication, conduction and use in diagnostic examinations.
- Sterile and non sterile gel medical devices for instrument lubrication, conduction and use in diagnostic examinations.
- Sterile eye drops for the alleviation of dry eyes.
- Pain relieving heat patches
- 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

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SIGNATURE PAGE

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Date (GMT)	Signed by	Reason
08-Oct-2018 14:39:31	Marrs Louise (LMarrs)	Signing as Approver