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Location: Moldova

Sagami Rubber Industries Co., Ltd.

2-1, Motocho, Atsugi-shi, Kanagawa
243-0002, Japan
Tel:+81-46-221-2311, Fax:+81-46-221-2315

April 28, 2022

Laboratoires Radiatex S.A.
137, Boulevard Voltaire
75011 Paris, France
Tel: +33 (0)1 56 06 41 53
Fax: +33 (0)1 56 06 41 54

Declaration of Conformity

Manufacturer: **SAGAMI RUBBER INDUSTRIES CO., LTD.**
2-1, Moto-cho, Atsugi-shi, Kanagawa-ken, 243-0002, JAPAN.

Sub-Contractor: **SAGAMI MANUFACTURERS SDN. BHD.**

Ipoh Factory:
No. 2, Jalan Kilang Tiga, Jelapang Light Industrial Estate, 30100 Ipoh, Perak, Malaysia.

Importer: **Laboratoires Radiatex S.A.**
137, Boulevard Voltaire 75011 Paris, France

European Authorized Representative: **SAGAMI EUROPE SARL.**
Les Cédres 89 Route de Molles 03300 Cusset, France

Product Descriptions

Product	:	Natural Rubber Latex Condoms (non-spermicidal device)
Classification	:	Class IIb
Classification Rules	:	Annex IX, Item 4, Special Rules 4, Rules 14
Conformity Assessment Path	:	Medical Devices Directives 93/42/EEC:2007 Annex II (Full Quality Assurance), Sect. 4 excluded
EC Certificate No.	:	G1 064193 0003 Rev. 01 (Valid until May 26, 2024)
GMDN Code	:	45138 (Basic male condom, Hevea-latex)
Brand name	:	Protex Classic Naturel Protex Classic Green Protex Stymuleve Protex Extra Large Protex Standard Plus Protex Standard Naturel Protex Classic Plus Fin Protex Anatomic Reel Protex Performance

Notified body : TÜV SÜD PRODUCT SERVICE GmbH (Identification no. 0123)
Ridlerstraße 65 · 80339 München Germany

SAGAMI

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Standards applied:

Standard Reference No.	Title of Standard
EN ISO 13485: 2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 4074: 2002	Natural latex rubber condoms – Requirements and test methods
EN 1041: 2008	Information supplied by the manufacturer of medical devices
EN ISO 15223-1: 2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN ISO 10993-1: 2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5: 2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
MEDDEV 2.7/1 Rev. 4	Guidelines on a medical devices: clinical evaluation
MEDDEV 2.12-1 rev.8	Guidelines on a medical devices: vigilance system

We herewith declare that the above mentioned products meet the provisions of the Council Directives 93/42/EEC as amended by 2007/47/EC.

All supporting documentation is retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the Declaration of Conformity.

Signature: .....

Satoshi ARIMA

Assistant General Manager, Quality Assurance Division
Sagami Rubber Industries Co., Ltd.

Date: April 28, 2022