Sagami Rubber Industries Co., Ltd.

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

June 8th, 2024

Laboratoires Radiatex S.A.
71-73 Rue Desnouettes
75015 Paris, France

Declaration of Conformity

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

SRN: **JP-MF-000040149**

Basic UDI-DI **4974234NRPBC0162**

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

Importer: **Laboratoires Radiatex S.A.**
71-73 Rue Desnouettes 75015 Paris, France

European Authorized Representative: **SAGAMI EUROPE**
Château de Brugheas 12 C Rue du Château 03700 Brugheas, France

Product Descriptions

Product	:	Natural Rubber Latex Probe cover
Classification	:	Class I
Classification Rules	:	REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 ANNEX VIII, Chapter III, Rules 5
Conformity Assessment Path	:	Annex II, III
Brand name	:	PROTEX PROBE COVER

Notified body: Not apply

Digitally signed by Granaci Boris
Date: 2025.10.02 15:43:22 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

SAGAMI

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Reference Standards:

Standard Reference No.	Title of Standard
EN ISO 13485:2016 + A11:2021	Medical devices – Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 4074:2015	Natural latex rubber condoms - Requirements and test methods
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General Requirements
EN ISO 14971:2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN ISO10993-1:2020	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
EN ISO10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
EN ISO10993-10:2023	Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-typed hypersensitivity
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
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 MDR.
All supporting documentation is retained under the premises of the manufacturer.
The manufacturer is exclusively responsible for the Declaration of Conformity.

Signature:

Satoshi Arima
Head of Quality Assurance Section

Date: June 8th, 2024

Yoshiaki Kawaguchi
Management Representative

June 8th, 2024

Address:

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Kanagawa-ken, 243-0002, Japan.