



## **EC Certificate**

Full Quality Assurance System Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) (Devices in Class IIa, IIb or III)

No. G1 064193 0003 Rev. 01

Manufacturer:

SAGAMI RUBBER INDUSTRIES CO., LTD.

2-1 Moto-Cho, Atsugi-Shi

Kanagawa-Ken 243-0002 JAPAN

Product Category(ies): Natural Rubber Latex Condoms

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

MYQMH0519093-721423244

Valid from:

2020-04-20

Valid until:

2024-05-26

Date.

2020-04-20

Christoph Dicks

Head of Certification/Notified Body