



Sagami Rubber Industries Co., Ltd.

2-1, Motocho, Atsugi-shi, Kanagawa

243-0002, Japan

Tel:+81-46-221-2311, Fax:+81-46-221-2315

November 22, 2022

DOETSCH GRETHER AG

Sternengasse 17, CH-4051 Basel, Switzerland

Declaration of Conformity
Ceylor and Celeste Natural Rubber Latex Condom

Manufacturer:

SAGAMI RUBBER INDUSTRIES CO., LTD.

2-1, Moto-cho, Atsugi-shi, Kanagawa-ken, 243-0002, Japan.

Sub-Contractor:

SAGAMI MANUFACTURERS SDN. BHD.

Batu Gajah Factory:

Plot 29, Lorong Bemban 4, Estet Perindustrian Bemban,
31000 Batu Gajah, Perak, Malaysia.

Ipoh Factory:

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

Importer:

DOETSCH GRETHER AG

Sternengasse 17, CH-4051 Basel, Switzerland

European Representative:

SAGAMI EUROPE

Les Cèdres 89 Route de Molles 03300 Cusset France.

(or)

Château de Brugheas 12 C Rue du Château 03700 Brugheas, 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 as amended by 2007/47/EC Annex II (Full Quality Assurance), Sect. 4 excluded
EC Certificate No.	: G1 064193 0003 Rev.01 (Valid until 2024-05-26)
GMDN Code	: 45138 (Basic male condom, Hever-latex)
Brand name	: Refer to the following list of products

No.	Brand Name	Article number
1	Ceylor Blauband 1er	05474.010.106.02
2	Ceylor Blauband 3er	05476.010.106.02
3	Ceylor Blauband 6er	05473.010.106.02
4	Ceylor Blauband 12er	05472.010.106.02
5	Ceylor Blauband 100er	05475.010.101.02
6	Ceylor Large 6er	05479.010.106.02
7	Ceylor Large 9er	05621.010.106.01
8	Ceylor Large 100er	05480.010.101.02
9	Ceylor Thin Sensation 6er	05481.010.106.02
10	Ceylor Thin Sensation 9er	05622.010.106.01
11	Ceylor Thin Sensation 12er	05619.010.106.01
12	Ceylor Thin Sensation 100er	05482.010.101.02
13	Ceylor Extra Feeling 6er	05483.010.106.02
14	Ceylor Extra Strong 6er	05485.010.106.02
15	Ceylor Extra Strong 100er	05486.010.101.02
16	Ceylor Tight Feeling 6er	05488.010.106.02
17	Ceylor Tight Feeling 100er	05487.010.101.02
18	Ceylor Easy Glide 6er	05489.010.106.02
19	Ceylor Easy Glide 9er	05623.010.106.01
20	Ceylor Easy Glide 100er	05490.010.101.02
21	Ceylor Strawberry 6er	05491.010.106.02
22	Ceylor Strawberry 100er	05492.010.101.02
23	Ceylor Fun Pack 6er	05484.010.106.02
24	Ceylor Fun Pack 100er	05596.010.101.01
25	Ceylor Rainbow Love 15	05620.010.104.01
26	Ceylor Super Large Glide 9	05680.010.106.01
27	Celeste Comfort 10	05824.010.105.01

Notified Body:

TÜV SÜD PRODUCT SERVICE GmbH (Identification no. 0123)

Ridlerstraße 65 · 80339 München Germany

Standards Applied: Refer to the following List of Reference Standards

Standard Reference No.	Title of Standard
EN ISO 13485:2016	Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016)
EN ISO 4074:2002	Natural latex rubber condoms - Requirements and test methods
EN 1041:2008	Information supplied by the manufacturer with 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 (ISO15223-1:2016, corrected version 2017-03).
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices (ISO 14971:2007, corrected version 2007-10-01)
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009).
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-typed hypersensitivity
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 for Medical Devices. 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



Yoshiaki Kawaguchi
Management Representative

Date:

November 22, 2022

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Address:

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