



Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# 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 005387 0003 Rev. 00**

**Manufacturer:** **Thai Nippon Rubber Industry Public  
Company Limited.**  
1 Charoenrat Road  
Thungwatdon, Sathon  
Bangkok 10120  
THAILAND

**EC-Representative:** Obelis S.A.  
Bd. Général Wahis 53, 1030 Brussels, BELGIUM

**Product Category(ies):** Natural rubber latex non-medicated male condoms used  
for contraception or the prevention of the transmission  
of sexually transmitted diseases  
  
Natural rubber latex non-medicated male condoms  
with tape applicator used for contraception or the  
prevention of the transmission of sexually transmitted  
diseases  
  
Non-sterile lubricating gel for condoms intended to  
improve lubrication

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.:** TH0161019T074

**Valid from:** 2019-04-17  
**Valid until:** 2022-02-11

**Date,** 2019-04-17

Stefan Preiß



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### Facility(ies):

Thai Nippon Rubber Industry Public Company Limited.  
1 Charoenrat Road, Thungwatdon, Sathon, Bangkok 10120,  
THAILAND

Thai Nippon Rubber Industry Public Company Limited.  
49-49/1, Factory Standard Building Export Zone 1, Laemchabang  
Industrial Estate, Moo 5, Thungsukhla, Sriracha, Chonburi 20230,  
THAILAND

Thai Nippon Rubber Industry Public Company Limited.  
789/139, Pinthong Industrial Estate Building, Moo 1, Nongkham,  
Sriracha, Chonburi 20110, THAILAND