

EU DECLARATION OF CONFORMITY

Manufacturer name **SURETEX LIMITED**

Manufacturing site address Registered Office and Factory:
31/1 Moo 4, Suratthani-Thakuapha Road
Tambon Khao Hua Kwai,
Amphur Phunphin,
Suratthani 84130
Thailand

EU Authorised representative **SXWell Belgium**, Riverside Business Park, Building I,
Internationalelaan 55, 1070 Brussels Belgium.

This declaration of conformity is issued under the sole responsibility of SURETEX LIMITED.

Product description Synthetic Polyisoprene Male Condoms lubricated with Non-spermicidal Lubricant

Brand name Please refer to Annex 1

Product name

Risk class Class IIb according to rule 14 annex IX

NBOG code MD 0107

Intended use Contraceptive device, invasive, single use

SURETEX LIMITED certified that the devices described above are in conformity with the Medical Device Directive 93/42/EEC OF THE COUNCIL as amended by Directive 2007/47/EC

References to common specifications used in relation to which conformity is declared (harmonized standard, non-harmonized standard, MEDDEV...):

- *ISO 23409,*
- *ASTM D3492 or harmonized standards*


Notify Body BSI NL 2797

Assessment procedure Annex II (excluded section 4)

Certificate number -issue number CE 525912 valid till 2022-11-21

GMDN code & term 34151 – Basic male condom, synthetic polymer

Approval

Date of issue	24 th May 2021
Place of the declaration	SURETEX LIMITED 31/1 Moo 4, Suratthani-Thakuapha Road Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130 Thailand
Signature/Date	 Herman Tsun Yuan Wang General Manager

ANNEX 1

List of CE Mark Product: Synthetic Polyisoprene Male Condoms lubricated with Non-spermicidal Lubricant, brand SKYN

Foiled Product Code	Item Code	Brand name	Product Name / Description
SS53PI/N/SL/98	200015	SKYN	MANIX SKYN ORIGINAL CONDOM BOX OF 144 GROSS BOX
SWD53PI/N/SL/98	200119	SKYN	MANIX SKYN 5 Senses condoms BX05
SS53PI/N/SL/Pa			MANIX SKYN 5 Senses condoms BX05
SS53PIU/N/SL/98			MANIX SKYN 5 Senses condoms BX05
SS53PI/N/VB/00			MANIX SKYN 5 Senses condoms BX05
SS53PI/N/SL/MM			MANIX SKYN 5 Senses condoms BX05
SS53PI/N/SLX/98			200133
SS56PI/N/SL/98	200134	SKYN	SKYN King Size condoms BX10
SS53PI/N/SL/98	200135	SKYN	SKYN Original condoms BX10
SWD53PI/N/SL/98	200136	SKYN	SKYN Intense Feel condoms BX10
SS53PIU/N/SL/98	200137	SKYN	SKYN Elite condoms BX10
SS53PIU/N/SL/98	200138	SKYN	SKYN Elite condoms BX20
SS53PI/N/SL/98	200139	SKYN	SKYN Original condoms BX20

REVISION HISTORY

Release #	Date	Summary of Changes	DCR Reference
00	2020/05/24	Initial release	240521/02