

## 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** Natural Rubber Latex Male Condoms lubricated with Non-spermicidal Lubricant  
**Brand name** Please refer to Annex 1  
**Product name**  
**Risk class** Class IIb according to Annex XI, rule 14  
**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 4074,*
- *ASTM D3492*
- *WHO 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** 45138 – Basic male condom, Hevea latex

**Approval**

Date of issue	24 <sup>th</sup> 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

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## ANNEX 1

List of CE Mark Product: Natural Rubber Latex Male Condoms lubricated with Non-spermicidal Lubricant, brand MANIX

Foiled Product Code	Item Code	Brand Name	Product Name/ Description
SS53/N/SL/99	300014	MANIX	MANIX NATURAL CONDOM BOX OF 24
SS52U/N/SL/99	300249	MANIX	Manix Super condoms BX14 Int.
SS53/N/SL/99	300252	MANIX	Manix Natural condoms BX14
DXR52/N/SL/99	300274	MANIX	Manix Xtra Pleasure condoms BX14 INT.

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### REVISION HISTORY

Release #	Date	Summary of Changes	DCR Reference
00	2021/05/24	Initial release	240521/02

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