


## EU Declaration of Conformity

for the Male Condom

### Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares, under their sole responsibility, that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Male Condom
Legal Manufacturer: (Name on Label)	<u>Nulatex Sdn Bhd</u> Lot 1870, 4th Mile Jalan Mengkibol 86000 Kluang, Johor Malaysia
SRN:	MY-MF-000018099
Basic UDI-DI:	955531350NSBMCHG. (Legacy Device)
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	To prevent pregnancy (contraception) and reduce the risk of sexually transmitted infections (STIs).
MDR Classification:	Class IIb [Rule 15]
EMDN Code:	U110101
Notified Body:	<u>BSI Group The Netherlands B.V.</u> Say Building, John M. Keynesplein 9, 1066 EP Amsterdam <b>NB Number: 2797</b>
CE Certificate Reference:	Not Yet Available
EU Authorised Representative:	<u>Advena Limited</u> Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Chapters I and III of Annex IX, and including an assessment of the technical documentation as specified in Section 4 of Annex IX

Name Ganesh Muniyandi Position QA/RA Manager  
Signed  Date 24/05/2024 Place Malaysia

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

#### Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications (CS):

Standard/CS/Document Name	Description
2017/745	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices
EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012 / ISO 14971:2019	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer - General requirements
EN ISO 20417:2021	Medical devices. Information to be supplied by the manufacturer

#### Appendix II – Product Listing/Schedule

##### 1.1.1 Own Brand (Feel)

VARIANT	UDI-DI	Pack qty
SMOOTH	9555313500521	3pcs
	9555313500606	12pcs
FRUTTI	9555313500576	3pcs
	9555313500651	12pcs
PROLONG	9555313500590	3pcs
	9555313500675	12pcs
XENSITIVE	9555313500538	3pcs
	9555313500613	12pcs
SEXY	9555313500552	3pcs
	9555313500637	12pcs
PLAYFUL	9555313500545	3pcs
	9555313500620	12pcs
BLISS	9555313500569	3pcs
	9555313500644	12pcs
BARE	9555313500682	3pcs
	9555313500712	12pcs
XTREME	9555313500699	3pcs
	9555313500736	12pcs
SMOOTH SNUG	9555313501252	3pcs
	9555313501269	12pcs
SMOOTH LARGE	9555313501276	3pcs
	9555313501283	12pcs

**1.1.2 Own Brand (Good Times)**

VARIANT	UDI-DI	Pack qty
SMOOTH	9555313500743	3pcs
	9555313500835	12pcs
ULTRATHIN	9555313500750	3pcs
	9555313500842	12pcs
STUDDDED	9555313500767	3pcs
	9555313500859	12pcs
RIBBED	9555313500774	3pcs
	9555313500866	12pcs
XENSATION	9555313500804	3pcs
	9555313500897	12pcs
FRUITEX	9555313500811	3pcs
	9555313500903	12pcs
PROLONG EXTRATHICK	9555313500828	3pcs
	9555313500910	12pcs

**1.1.3 Topi**

VARIANT	UDI-DI	Pack qty,
Smooth	9555313500965	2pcs
Dotted	9555313501009	2pcs
Ribbed	9555313500972	2pcs
Ultrathin	9555313500996	2pcs
Extrathick	9555313500989	2pcs
Smooth,Dotted,Ribbed	9555313500484	144pcs
Smooth,Dotted,Ribbed	9555313500491	100pcs
Smooth,Dotted,Ribbed, Extra thick,Ultrathin	9555313501911	36x2pcs

**1.1.4 OEM Brands (Matrix,)**

VARIANT	UDI-DI	Pack qty
Smooth	9555313509517	144pcs
Smooth	8436029313098	144pcs

**1.1.5 OEM Brands (Yosi)**

VARIANT	UDI-DI	Pack qty, 50pcs bulk pack
YOSI XXL	4013006258777	50pcs
YOSI X-TRA	4013006258760	50pcs
YOSI Regular Natural Dry	4013006258746	50pcs
YOSI Regular Natural Lubricated	4013006258753	50pcs
YOSI Ultrathin	4013006258722	50pcs
YOSI Ribbed	4013006258715	50pcs
YOSI Mixed	4013006258739	50pcs

**1.1.6 OEM Brands (Kondomotheke)**

VARIANT	UDI-DI	Pack qty, 100pcs bulk pack
BASIC 100	4260233387200	100pcs
BLACK 100	4260233387217	100pcs
MAXI 100	4260233387224	100pcs
MEGA 100	4260233387262	100pcs
SAFE 100	4260233387279	100pcs
TIGHT 100	4260233387231	100pcs
XTREM 100	4260233387248	100pcs
DRY 100	4260233387255	100pcs
THIN 100	4260233387286	100pcs

**1.1.7 OEM Brands (Secura/ORION)**

VARIANT	UDI-DI	Pack qty,
ORIGINAL	4024144281053	48pcs
EXTRA FEEL	4024144281466	48pcs
EXTRA FUN	4024144281497	48pcs
EXTRA LARGE	4024144281619	48pcs
EXTRA WET	4024144282647	48pcs
EXTRA SAFE	4024144282678	48pcs
ORION BEST MATE	4024144282708	48pcs
ORION BEST MATE(MIX)	4024144282814	48pcs



ORIGINAL	4024144281046	12pcs
EXTRA FEEL	4024144281459	12pcs
EXTRA FUN	4024144281480	12pcs
EXTRA LARGE	4024144281602	12pcs
EXTRA WET	4024144282630	12pcs
EXTRA SAFE	4024144282661	12pcs
ORION BEST MATE	4024144282692	12pcs
ORIGINAL	4024144281107	100pcs
EXTRA FEEL	4024144281473	100pcs
EXTRA FUN	4024144281596	100pcs
EXTRA LARGE	4024144281626	100pcs
EXTRA WET	4024144282654	100pcs
EXTRA SAFE	4024144282685	100pcs
ORIGINAL	4024144281114	1000pcs

#### 1.1.8 OEM Brands (Loverellia)

VARIANT	UDI-DI	Pack qty
STRONG/STARK	4250784924306	50pcs per poly bag
MIX	4250784924313	50pcs per poly bag
DRY/TROKEN	4250784924290	50pcs per poly bag
49MM	4250784924634	50pcs per poly bag
Natural Feeling	4250784925662	50pcs per poly bag
Extra Groß	4250784925679	50pcs per poly bag
Extra Dünn	4250784925686	50pcs per poly bag
Länger Lieben	4250784926058	50pcs per poly bag

#### 1.1.9 OEM Brands (Parachute)

VARIANT	UDI-DI	Pack qty
KLASIK	8690555680899	12pcs
TIRTIKLI	8690555680905	12pcs
INCE	8690555680929	12pcs

#### Version History

Version	Compiled by	Date	Description
1.0	Samuel Attard		Initial Issue