

## EU DECLARATION OF CONFORMITY

Manufacturer name	SURETEX LIMITED
SRN	TH-MF-000001364
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.
SRN	BE-AR-000001272
<b>This declaration of conformity is issued under the sole responsibility of SURETEX LIMITED.</b>	
Product description	Synthetic Polyisoprene Latex Condom
Basic UDI number	5011831Plcondom-NMLubC5
Brand name	See Annex 1
Product name	See Annex 1
Risk class	Class IIb according to Annex VIII, Rule 15
NBOG code	MDN 1210
Intended use	Contraceptive purposes and to help protect against sexually transmitted infections They are an invasive (natural body orifice), single use device.

**SURETEX LIMITED certified that the devices described above are in conformity with the Medical Device Regulation 745/2017/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

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

- No common specification is available for Synthetic Polyisoprene Latex Condom
- ISO 23409

Assessment procedure Annex IX Chapter I & III (FQA)

EC Certificate (Annex IX) FQA No: MDR 744261

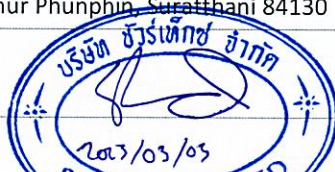
Issued by: BSI Netherlands (NB No: 2797) First Issued on: 22-11-04

Current Issue No: 01 Dated: 22-11-04

GMDN code & terms 34151 Basic Male Condom, synthetic polymer

EMDN code & terms U110101- Condoms

## Approval

Date of issue	14 February 2023
Place of the declaration	SURETEX LIMITED 31/1 Moo 4, Suratthani-Thakuapha Road Tambon Khao Hua Kwai, Amphur Phunphin, Suratthani 84130 Thailand
Signature/Date	 Steven Greenwood General Manager

## ANNEX I

## List of CE Mark Product – Synthetic Polyisoprene Latex Condom-Germany

LS internal code	MAPA Item Code	Factory Product Code	Brand Name	GTIN	Product Name/ Description
200191	11131105	SS53PI/N/SL/99	BILLY BOY SKYN	4008600270386	BILLY BOY SKYN HAUTNAH IER SAMPLE
200192	11134452	SS53PI/N/SL/99	BILLY BOY SKYN	4008600260899	BILLY BOY SKYN HAUTNAH 8ER PACK
200192	11134488	SS53PI/N/SL/99	BILLY BOY SKYN	4008600419198	BILLY BOY SKYN Hautnah 10er Pack NEU
200192	11133049	SS53PI/N/SL/99	BILLY BOY SKYN	4008600287865	BILLY BOY SKYN HAUTNAH 40ER BOX
200193	11134453	SS53PI/N/SLX/99	BILLY BOY SKYN	4008600261018	BILLY BOY SKYN HAUTNAH EXTRA FEUCHT 8ER
200193	11134489	SS53PI/N/SLX/99	BILLY BOY SKYN	4008600419167	BILLY BOY SKYN Hautnah extra feucht 10er Pack NEU
200194	11131109 11134319	SWD53PI/N/SL/99	BILLY BOY SKYN	4008600368625	BILLY BOY SKYN HAUTNAH PERLGENOPPT IER SAMPLE
200195	11134319	SWD53PI/N/SL/99	BILLY BOY SKYN	4008600368588	BILLY BOY SKYN HAUTNAH PERLGENOPPT 8ER PACK
200195	11134490	SWD53PI/N/SL/99	BILLY BOY SKYN	4008600419150	BILLY BOY SKYN Hautnah perlgenoppt 10er Pack NEU