European Medical Device Regulation 2017/745 Concerning Medical Devices

This declaration of conformity is issued under the sole responsibility of Innolatex (Thailand) Limited.

We, hereby declare that Innolatex (Thailand) Limited is the natural and legal person with responsibility for the design, manufacture, packaging, and labelling before the device(s) are placed on the market under our name, regardless of whether these operations are carried out by the Manufacturer or on his behalf by a third party.

General Product Name:	Non-sterile, Non-medicated Synthetic Nitrile Male Condoms
Manufacturer:	Innolatex (Thailand) Limited E1-6 Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-District, Hatyai District, Songkhla 90110 Thailand. (*Single Registration Number: TH-MF-000001249*)
Product Variant:	As shown in Annex I: Product Variants
Trade Name:	As shown in Annex II: Brand Listing
Intended Use/Purpose:	For contraception and prevention of sexually transmitted infections.
Standards tested to:	As shown in Annex III: Harmonised Standard
EU MDR 2017/745 Classification No. & Rule:	Class IIb, Rule 15.
EU MDR 2017/745 Assessment route:	Annex IX (Chapter I & III)
Basic UDI-DI:	88586938-NMSNCM-FX
EMDN/CND Code:	U110101
Notified Body:	TUV SUD Product Service GmbH (0123) Zertifizierstelle Ridlerstraβe 65, 80339 MÜNCHEN, Germany
EU Authorised Representative:	Advena Ltd. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta. *(Single Registration Number: MT-AR-000000234)*
EC Certificate Number:	G10 105104 0004 Rev.00

The undersigned declares that the products referenced in this document is in conformity with the Regulation (EU) 2017/45 and if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Signed on behalf of Innolatex (Thailand) Limited

.....

Khairunnisa Warsito
Group RA Manager
Port Klang, Selangor, Malaysia

บริษัท อินโนลาเท็กซ์ (ประเทศไทย) จำกัด
Innolatex (Thailand) Limited

Date 19.08.2024

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

E 1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-district, Hatyai District, Songkhla, Thailand 90110
บริษัท อินโนลาเท็กซ์ (ประเทศไทย) จำกัด อี 1-6 เขตอุตสาหกรรมส่งออก นิคมอุตสาหกรรมภาคใต้ หมู่ 4 ตำบลฉลุง, หาดใหญ่, สงขลา, 90110
T: +66 (0) 7420 6111 F: +66 (0) 7420 6112 E-mail: itl@karex.com.my Website: karex.com.my

Issuance History

Issue No	Compiled by	Date	Description
00	Wan Husna	19.08.2024	1. Initial issue of Declaration of Conformity

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

E 1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-district, Hatyai District, Songkhla, Thailand 90110
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Annex I: Product Variant

Product Types	Configuration	Surface	Colour	Flavours	Masking
P53SHS NLN XEST	Parallel Sided	Smooth	Natural	Non-Flavoured	None
P56SHS NLN XNST	Parallel Sided	Smooth	Natural	Non-Flavoured	None
P60SHS NLN XNST	Parallel Sided	Smooth	Natural	Non-Flavoured	None

Signed: ..... **Date:** 19.08.2024

Khairunnisa Warsito
Group RA Manager
Port Klang, Selangor, Malaysia

INNOLATEX (THAILAND) LIMITED
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Issuance History

Issue No.	Compiled by	Date	Description
00	Wan Husna	19.08.2024	1. Initial issuance of Annex I: Product Listing

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

E 1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-district, Hatyai District, Songkhla, Thailand 90110
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Annex II: Brand Listing

Importer	Brand Name	Sub-brand	Customer Reference Number	Product Code	Size or Packing Mode	UDI-DI	Region/ Country Code
Reckitt Benckiser France	Durex	Intensity	3302786	P56SHS NLN XNST	5's	I:3059948010661	FR, PT
	Durex	Intensity	3302788	P56SHS NLN XNST	10's	I:3059948010678	FR, PT
	Durex	Intensity	3302789	P56SHS NLN XNST	20's	I:3059948010685	FR, PT
	Durex	Intensity XL	3302790	P60SHS NLN XNST	10's	I:3059948010692	FR, PT

Remark for abbreviations: < F = Foil, I = Inner, O = Outer, C = Carton>

Signed: _____ **Date:** 19.08.2024

Khairunnisa Warsito
Group RA Manager
Port Klang, Selangor, Malaysia

บริษัท อินโนลาเท็กซ์ (ประเทศไทย) จำกัด
Innolatex (Thailand) Limited

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

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Issuance History

Issue No.	Compiled by	Date	Description
00	Wan Husna	19.08.2024	1. Initial issuance of Annex II: Brand Listing

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

E 1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-district, Hatyai District, Songkhla, Thailand 90110
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Annex III: Harmonised Standard

No.	Reference No.	Title
1.	ISO 23409:2011	Male Condoms – Requirements and Test Methods for Condoms Made from Synthetic Materials.
2	ISO 29943-1:2017	Condoms – Guidance on Clinical Studies – Part 1: Male Condoms, Clinical Function Studies Based on Self-Reports
3.	ISO 10993-1:2018	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
4.	ISO 10993-5:2009	Biological evaluation of medical devices. Tests for in vitro cytotoxicity.
5.	ISO 10993-10:2021	Biological evaluation of medical devices. Tests for skin sensitization.
6.	ISO 10993-11:2017	Biological evaluation of medical devices. Tests for Systemic Toxicity
7.	ISO 10993-18:2020	Biological evaluation of Medical Device - Part 18: Chemical characterization of materials
8.	ISO 10993-23:2021	Biological evaluation of medical devices. Tests for irritation.
9.	ISO 14971:2019/ EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
10.	ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
11.	ASTM D7661-23	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
12.	ISO 29941:2010	Condoms - Determination of nitrosamines migrating from natural rubber latex condoms
13.	ISO 2859-1:1999	Sampling procedures for inspection by attributes -- Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
14.	ASTM D4169-23	Standard Practice for Performance Testing of Shipping Containers and Systems
15.	EN ISO 13485:2016 + A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
16.	USP 61	Microbiological Examination of Nonsterile Products: Microbial Enumeration Tests
17.	USP 62	Microbiological Examination of Nonsterile Products: Test for Specified Microorganisms
18.	Version 1.22 dated 05-2019	Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices
19.	MEDDEV 2.7/1 Rev 4 (June 2016)	Clinical evaluation: Guide for manufacturers and notified bodies
20.	MEDDEV 2.12/1 Rev 8 (January 2013)	Medical Devices Vigilance System
21.	MEDDEV 2.12/2 Rev 2 (January 2012)	Post Market Clinical Follow-up studies

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No.	Reference No.	Title
22.	MDCG 2020-7 (April 2020)	Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies
23.	MDCG 2020-8 (April 2020)	Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies

Signed: _____ **Date:** 19.08.2024

Khairunnisa Warsito
Group RA Manager
Port Klang, Selangor, Malaysia

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

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Issuance History

Issue No.	Compiled by	Date	Description
00	Wan Husna	19.08.2024	1. Initial issuance of Annex III: Harmonised Standard

INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2

E 1-6, Export Processing Zone, Southern Industrial Estate, Village 4, Chalung Sub-district, Hatyai District, Songkhla, Thailand 90110
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00. T-DOC-05_Declaration of Conformity_Issue No. 00_19.08.2024-Master

Final Audit Report 2024-08-19

Created:	2024-08-19
By:	Wan Husna Afiqah Binti Wan Roskhemai (wan.husna@karex.com.my)
Status:	Signed
Transaction ID:	CBJCHBCAABAAuG67jUtt9ceCSNvbEZN9tBiiN1kZHY-N

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Annex II: Brand Listing

Importer	Brand Name	Sub-brand	Customer Reference Number	Product Code	Size or Packing Mode	UDI-DI	Region/ Country Code
Reckitt Benckiser France	Durex	Intensity	3302786	P56SHS NLN XNST	5's	I:3059948010661	FR
	Durex	Intensity	3302788	P56SHS NLN XNST	10's	I:3059948010678	FR
	Durex	Intensity	3302789	P56SHS NLN XNST	20's	I:3059948010685	FR
	Durex	Intensity XL	3302790	P60SHS NLN XNST	10's	I:3059948010692	FR
RB NL Brands B.V.	Durex	Intensity	3302791	P56SHS NLN XNST	5's	I:8710552315546	BE, NL, LU
	Durex	Intensity	3302792	P56SHS NLN XNST	10's	I:8710552315553	BE, NL, LU
	Durex	Intensity	3302793	P56SHS NLN XNST	20's	I:8710552315560	BE, NL, LU
	Durex	Intensity XL	3302794	P60SHS NLN XNST	10's	I:8710552315570	BE, NL, LU

Remark for abbreviations: < F = Foil, I = Inner, O = Outer, C = Carton>

Signed: _____ **Date:** 27.08.2024

Khairunnisa Warsito
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INNOLATEX (THAILAND) LIMITED
0-9055-46001-69-2
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Issuance History

Issue No.	Compiled by	Date	Description
00	Wan Husna	19.08.2024	1. Initial issuance of Annex II: Brand Listing
01	Wan Husna	27.08.2024	1. Add new brand Durex Intensity for the BENELUX (BE, NL, LU) market. 2. Remove the “PT” market for Durex Intensity and Intensity XL imported by Reckitt Benckiser France.

INNOLATEX (THAILAND) LIMITED
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Final Audit Report 2024-08-29

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Transaction ID:	CBJCHBCAABAAIjJNw-KosWdjrpipOTvAvQBwP9_nNVHz

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