Declaration of Conformity

The European Declaration of Conformity is under the sole responsibility of the manufacturer.

The devices covered by this present declaration are in conformity with Medical Device Regulation (EU) 2017/745.

Device Identification

Device Name: Natural Rubber Latex Condoms with Silicone Lubricant

Brands: Durex, London

File Reference: MDR011

Issue Number: 2.0

Component Number: see table below

Global Product Name	Description Shape, texture, Colour	Generic Product Assembly (GPA) Code	Condom Type	Lubricant Type	Date of First CE mark under Medical Device Regualtion (EU) 2017/745
Durex NRL AP Easy On Standard Condom	Easy-on, smooth, transparent	GPA50003309 (BPK) GPA50008590 (SMA)	CON 28	LUB 72	16th December 2024
		GPA50003269 (BPK) GPA50008578 (SMA)	CON 28	LUB 73	16th December 2024
		GPA50003270 (BPK)	CON 28	LUB 95	16th December 2024
Durex NRL AP Easy On Thick Condom	Easy-on, smooth, transparent	GPA50003312 (BPK) GPA50008594 (SMA)	CON 34	LUB 95	16th December 2024
Durex NRL AP Easy On Thin Condom	Easy-on, smooth, transparent	GPA50003271 (BPK) GPA50008588 (SMA)	CON 33	LUB 72	16th December 2024
		GPA50003662 (BPK) GPA50020503 (SMA)	CON 96	LUB 72	16th December 2024
Durex NRL Easy On Standard Condom	Easy-on, smooth, transparent	GPA50003277 (BPK) GPA50008586 (SMA)	CON 10	LUB 73	16th December 2024

Reckitt Benckiser Healthcare (UK) Limited

Dansom Lane

Hull

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United Kingdom

T: +44 (0)1482 326151 **W:** Reckitt.com

Registered in England, No. 6270876 Registered office at 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom

Global Product Name	Description Shape, texture, Colour	Generic Product Assembly (GPA) Code	Condom Type	Lubricant Type	Date of First CE mark under Medical Device Regualtion (EU) 2017/745
Durex NRL Easy On Textured Condom	Easy-on, textured, transparent	GPA50003266 (BPK) GPA50008585 (SMA)	CON 24	LUB 73	16th December 2024
Durex NRL Easy On Thick Condom	Easy-on, smooth, transparent	GPA50003264 (BPK) GPA50008580 (SMA)	CON 26	LUB 73	16th December 2024
		GPA50003268 (BPK) GPA50008587 (SMA)	CON 26	LUB 95	16th December 2024
Durex NRL Easy On Thin Condom	Easy-on, smooth, transparent	GPA50003275 (BPK) GPA50008576 (SMA) GPA50008577 (SMA)	CON 9	LUB 73	16th December 2024
		GPA50003276 (BPK) GPA50008570 (SMA)	CON 9	LUB 95	16th December 2024
		GPA50003607 (BPK) GPA50006449 (SMA)	CON 94	LUB 72	16th December 2024
		GPA50003618 (BPK) GPA50020502 (SMA)	CON 94	LUB 73	16th December 2024
Durex NRL Easy On Ultra Thin Condom	Easy-on, smooth, transparent	GPA50033994 (SMA)	CON95	LUB72	16th December 2024
		GPA50033998 (SMA)	CON95	LUB73	16th December 2024
		GPA50022328 (SMA)	CON100	LUB72	16th December 2024
		GPA50022329 (SMA)	CON100	LUB73	16th December 2024
Durex NRL Easy On Ultra Thin Condom	Easy-on, smooth, transparent	GPA50019154 (SMA)	CON101	LUB72	16th December 2024
Durex NRL Easy On XL Standard Condom	Easy-on, smooth, transparent	GPA50003265 (BPK)	CON 23	LUB 95	16th December 2024
Durex NRL Extra Large Easy On Thin Condom	Easy-on, smooth, transparent	GPA50020217 (BPK)	CON98	LUB72	16th December 2024
		GPA50006259 (BPK)	CON104	LUB72	16th December 2024
Durex NRL Straight Wall	Straight walled,	GPA50003272 (BPK) GPA50008571 (SMA) GPA50008575 (SMA)	CON 62	LUB 72	16th December 2024

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Global Product Name	Description Shape, texture, Colour	Generic Product Assembly (GPA) Code	Condom Type	Lubricant Type	Date of First CE mark under Medical Device Regualtion (EU) 2017/745
Extra Thin Condom	smooth, transparent	GPA50008579 (SMA)			
		GPA50000423 (BPK) GPA50008581 (SMA) GPA50008584 (SMA)	CON 62	LUB 73	16th December 2024
		GPA50005655 (BPK) GPA50014642 (SMA)	CON106	LUB72	16th December 2024
Durex NRL Straight Wall Standard Condom	Straight walled, smooth, transparent	GPA50003273 (BPK) GPA50008582 (SMA)	CON 2	LUB 72	16th December 2024
Durex NRL Straight Wall Textured Condom	Straight walled, dotted, transparent	GPA50003281 (BPK)	CON 14	LUB 72	16th December 2024
Durex NRL Straight Wall Thin Condom	Straight walled, smooth, transparent	GPA50003119 (BPK) GPA50008592 (SMA)	CON 1	LUB 72	16th December 2024
		GPA50008589 (SMA) GPA50008614 (SMA)	CON 72	LUB 72	16th December 2024
		GPA50008596 (SMA) GPA50008609 (SMA)	CON 72	LUB 73	16th December 2024
		GPA50008583 (SMA)	CON 73	LUB 73	16th December 2024
London NRL Straight Wall Standard Condom	Straight walled, smooth, transparent	GPA50008574 (SMA)	CON 13	LUB 72	16th December 2024

Key
NRL – Natural Rubber Latex
AP – Asia Pacific
XL – Extra Large

Basic UDI: 5000158MDR011AQ

EMDN Code: U110101

Reckitt Benckiser Healthcare (UK) Limited

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Legal Manufacturer

Name: Reckitt Benckiser Healthcare (UK) Ltd

Address: Dansom Lane
Hull
HU8 7DS

Country: United Kingdom

SRN: GB-MF-000035615

Authorised Representative:

Name: Reckitt Benckiser NL Brands B.V

Address: Schiphol Boulevard 207
1118 BH Schiphol

Country: The Netherlands

SRN: NL-AR-000006055

Registration Information

Notified Body ID: 1639

Notified Body Address: SGS House, Noorderlaan 87, 2030 Antwerp, Belgium

Identification of the certificate(s) issued by the notified body: GB24/00000191

Date CE marked: See device identification table above.

Conformity Assessment

Device Classification:	Class IIb, according to Rule 15 of Annex VIII of the Medical Device Regulation (EU) 2017/45
Conformity Assessment Route:	Medical Device Regulation (EU) 2017/745 Annex IX
Applicable Legislative Acts:	Refer to Appendix 1 of the European Declaration of Conformity

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Intended Use

These devices achieve their intended use via a physical mode of action. The intended use of the device is to act as a method of contraception and prevent transmission of sexually transmitted infections.

Reckitt Benckiser Healthcare (UK) Ltd. declares that the above-mentioned devices are in conformity with Annex I General Safety and Performance Requirements and the provisions of Medical Device Regulation (EU) 2017/745 and conforms to the legislative acts detailed in Appendix 1 of the European Declaration of Conformity.

Signature

Name: Mark Ainsworth

Function: Regulatory Operations Senior Manager

Signature: 

Electronically signed by: Mark Ainsworth
Reason: I approve this document.
Date: Oct 3, 2025 11:54:33 GMT+1

Date: 03-Oct-2025

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Appendix to the European Declaration of Conformity

Appendix 1: Applicable Legislative acts

Directives / Regulations

Directive/Regulation Number	Directive/Regulation Name
Regulation (EU) 2017/745	European Medical Device Regulation

Harmonised Standards

Standard Number and Date	Standard Name
EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
EN ISO 10993-18:2020/A1:2023	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements

Other Applicable Standards

Standard Number and Date	Standard Name
BS EN ISO 13485:2016+A11:2021	Medical Devices. Quality Management Systems – Requirements for regulatory purposes
BS EN ISO 14971:2019+A11:2021	Medical devices. Application of risk management to medical devices

Standard Number and Date	Standard Name
PD CEN ISO/TR 24971:2020	Medical devices. Guidance on the application of ISO 14971.
BS EN ISO 4074:2015	Natural rubber latex male condoms. Requirements and test methods.
BS EN ISO 10993-1:2020	Biological evaluation of medical devices. Evaluation and testing within a risk management process.
BS EN ISO 10993-5:2009+A11:2025	Biological Evaluation of medical devices. Tests for *in vitro* cytotoxicity.
BS EN ISO 10993-10:2023	Biological evaluation of medical devices. Tests for skin sensitization
BS EN ISO 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity
BS EN ISO 10993-17:2023	Biological evaluation of medical devices. Toxicological risk assessment of medical device constituents
BS EN ISO 10993-18:2020+A1:2023	Biological evaluation of medical devices. Chemical characterization of medical device materials within a risk management process.
BS EN ISO 10993-23:2021	Biological evaluation of medical devices, Tests for irritation
BS EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
BS EN ISO 15223-1:2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer. General requirements
BS EN 62366-1:2015+A1:2020	Medical devices. Application of usability engineering to medical devices
ISO 14155:2020	Clinical investigation of medical devices for human subjects – Good Clinical Practice

Guidance, Common Specifications, Implementing Acts & Delegated Acts

Number or Reference of Document	Name of Document	Date & Version
MEDDEV 2.7/1 rev.4	Clinical Evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC	June 2016, Revision 4
MEDDEV 2.12/1 rev.8	Guidelines on a medical devices vigilance system Additional guidance regarding the vigilance system	January 2013 July 2019, Revision 8
MDCG 2020-5	Clinical Evaluation - Equivalence A guide for manufacturers and notified bodies	April 2020
MDCG 2020-6	Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies	April 2020
MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template. A guide for manufacturers and notified bodies	April 2020
MDCG 2020-8	Post-market clinical follow-up (PMCF) Evaluation Report Template. A guide for manufacturers and notified bodies	April 2020
MDCG 2021-24	Guidance on classification of medical devices	October 2021

Number or Reference of Document	Name of Document	Date & Version
Commission Implementing Decision (EU) 2022/6	Commission Implementing Decision (EU) 2022/6 of 4 January 2022 amending Implementing Decision (EU) 2021/1182 as regards harmonised standards for biological evaluation of medical devices, sterilisation of health care products, aseptic processing of health care products, quality management systems, symbols to be used with information to be supplied by the manufacturer, processing of health care products and home light therapy equipment	4th Jan 2022
MDCG 2018-1 rev.4	Guidance on basic UDI-DI and changed to UDI-DI	April 2021
MDCG-2018-6	Clarification of UDI related responsibilities in relation to article 16	October 2018
MDCG 2019-1	MDCG guiding principles for issuing entities rules on basic UDI-DI	January 2019
MDCG 2020-13	Clinical evaluation assessment report template	July 2020
MDCG 2021-10	The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices	June 2021
MDCG 2021-19	Guidance note integration of the UDI within an organisation's quality management system	July 2021
MDCG 2022-7	Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746	May 2022

Appendix 2: Variants and Pack Sizes

Natural Rubber Latex Condoms with Silicone Lubricant are sold in the following variants and Pack sizes in the European Union.

Individual Pack Sizes

GPA Code	Local Device Name	Market	Pack Size
GPA50006449	Durex Gefühlsecht Classic	Austria	40
GPA50008582	London Q600		100, 1000
GPA50014642	Durex Gefühlsecht Extra Dünn		8, 10, 30
GPA50020217	Durex Hautnah XXL		8, 10
GPA50022328	Durex Hautnah Ultra Dünn		8, 10
GPA50033994	Durex Hautnah Classic		1, 8
GPA50003607	Durex Thin Feel	Belgium	12, 20, 144
GPA50008585	Durex Pleasure Me		10
GPA50008586	Durex Originals Classic Natural		10, 12, 20
GPA50020502	Durex Feeling Extra		40
GPA50022328	Durex Nude Classic		10, 20
GPA50003266 (BPK) GPA50008585 (SMA)	Durex Pleasure Me	France	BPK : 2, 12, 20 SMA : 2, 12, 20, 40
GPA50003269 (BPK) GPA50008587 (SMA)	Durex Classic Protect		BPK : 6 SMA : 6
GPA50003277 (BPK) GPA50008586 (SMA)	Durex Classic Jeans		BPK : 12 SMA : 3, 12, 20, 40
GPA50003607	Durex Feeling		144
GPA50006259	Durex Feeling XL		10
GPA50020217	Durex Nude XL		2
GPA50003618 (BPK) GPA50020502 (SMA)	Durex Feeling Extra		BPK :12, 20, 40 SMA : 12,20,40
GPA50022328	Durex Nude		1, 10, 20
GPA50006449	Durex Gefühlsecht Classic	Germany	40
GPA50008582	London Q600		100, 1000
GPA50014642	Durex Gefühlsecht Ultra Dünn		8, 10, 30
GPA50020217	Durex Hautnah XXL		8, 10
GPA50022328	Durex Hautnah Ultra Dünn		8, 10
GPA50033994	Durex Hautnah Classic		1, 8
GPA50008585	Durex Pleasuremax	Greece	6, 10, 30
GPA50022328	Durex Invisible		12
GPA50008586	Durex Originals óvszer	Hungary	3, 4, 12
GPA50019154	Durex Invisible		10
GPA50020502	Durex Feel Intimate óvszer		3, 6, 12, 18
GPA50022328	Durex Invisible óvszer		10
GPA50003662	Durex Thin Feel Close Fit	Ireland	12, 30
GPA50006259	Durex Thin Feel Extra Large		12, 30

GPA Code	Local Device Name	Market	Pack Size
GPA50006449	Durex Thin Feel		3, 6, 12, 20, 30, 40
GPA50020217	Durex Nude Extra Large		12
GPA50022328	Durex Nude Ultra Thin		6, 12, 30
GPA50003607 (BPK) GPA50006449 (SMA)	Durex Thin Feel		BPK : 3, 6, 12, 20, 30, 40 SMA : 3
GPA50008585	Durex Pleasure Me		6, 12, 20
GPA50008587	Durex Originals Extra Safe		3, 12, 20, 30
GPA50014642	Durex Thin Feel Ultra Thin		12
GPA50019154	Durex Nude Ultra Thin - Close Fit		12
GPA50022329	Durex Nude Ultra Thin Extra Lube		12
GPA50003265	Durex Jeans XL	Italy	5, 10
GPA50003277	Durex Jeans		3, 6, 10, 27
GPA50003607 (BPK) GPA50006449 (SMA)	Durex Supersottile vestibilità regular		BPK : 6, 10, 12, 18 SMA : 10
GPA50003662 (BPK) GPA50020503 (SMA)	Durex Supersottile vestibilità aderente		BPK : 6, 10 SMA :10
GPA50006259	Durex Supersottile XL		6, 10
GPA50008578	Durex Settebello classico		3 ,6 10, 12, 18, 27, 40
GPA50008585	Durex Pleasure Max		6, 10, 30
GPA50008586	Durex Jeans		6, 9, 10, 12, 27
GPA50008587	Durex Extra Sicuro		10
GPA50020217	Durex Invisible XL		6
GPA50022328	Durex Invisible vestibilità regular		6, 10
GPA50003607	Durex Thin Feel	Luxembourg	12, 20, 144
GPA50008585	Durex Pleasure Me		10
GPA50008586	Durex Originals Classic Natural		10, 12, 20
GPA50020502	Durex Feeling Extra		40
GPA50022328	Durex Nude Classic		10, 20
GPA50003265	Durex Intense Delight	Malta	3, 12
GPA50003273	Durex Original Close Fit		3, 12
GPA50003275	Durex Condom Thin Feel		12
GPA50008585	Durex Pleasure Me		6
GPA50008587	Durex Originals Extra Safe		3
GPA50003607	Durex Thin Feel	Netherlands	12, 20, 144
GPA50008585	Durex Pleasure Me		10
GPA50008586	Durex Originals Classic Natural		10, 12, 20
GPA50020502	Durex Feeling Extra		40
GPA50022328	Durex Nude Classic		10, 20
GPA50003277	Durex Natural	Portugal	144
GPA50003618	Durex Sensitivo Suave		12, 24, 144
GPA50003662	Durex Sensitivo Slim Fit		10
GPA50006259	Durex Sensitivo XL		10

GPA Code	Local Device Name	Market	Pack Size
GPA50008585	Durex Dá-me Prazer		3, 12
GPA50008586	Durex Natural		3, 6, 12, 24
GPA50008587	Durex Extra Seguro		12
GPA50014642	Durex Sensitivo Super Fino		6, 12
GPA50020217	Durex Invisible XL		10
GPA50020502	Durex Sensitivo Suave		3
GPA50022328	Durex Invisible		3, 12, 24
GPA50022329	Durex Invisible Extra Lubrificado		12
GPA50008586	Durex Originals kondomi	Slovenia	3, 12
GPA50003277	Durex Natural	Spain	144
GPA50003618	Durex Sensitivo Suave		12, 24, 144
GPA50003662	Durex Sensitivo Slim Fit		10
GPA50006259	Durex Sensitivo XL		10
GPA50008582	Durex Natural Slim Fit		144
GPA50008585	Durex Dame Placer		3, 12
GPA50008586	Durex Natural		3, 6, 12, 24
GPA50008587	Durex Extra Seguro		12
GPA50014642	Durex Sensitivo Super Fino		6, 12
GPA50020217	Durex Invisible XL		10
GPA50020502	Durex Sensitivo Suave		3
GPA50022328	Durex Invisible		3, 12, 24
GPA50022329	Durex Invisible Extra Lubricado		12

Mixed Pack Sizes

The mix packs listed contain devices whose conformity has been assessed under different technical files; the corresponding technical files are as detailed. The safety, efficacy and compliance data supporting substantiating the devices are therefore presented in different technical files depending in which family the device resides. For all technical files, the legal manufacturer is Reckitt Benckiser Healthcare (UK) Ltd. therefore all the data is held in one centralized location.

GPA Code	Local Device Name	Market	Pack Size	MDTF Ref.
GPA50003271 + GPA50003275 + GPA50003265	Durex Fit Lab	Austria Germany	3 (1, 1, 1)	MDR011 MDR011 MDR011
GPA50003266 + GPA50003618 + GPA50003662 + GPA5000032	Durex Fun Explosion	Belgium France Italy Luxembourg Netherlands	40 (10, 10, 10, 10)	MDR011 MDR011 MDR011 MDR002
GPA5000021 + GPA5000032 + GPA50003266 + GPA50004381 + GPA50003618	Durex Love Mix	Austria Germany	18 (4, 4, 4, 2, 4)	MDR003 MDR002 MDR011 MDR004 MDR011
GPA5000032 + GPA50003607 + GPA0003280 + GPA50003281	Durex Mix Sorpresa	Italy	30 (10, 8, 6, 6)	MDR002 MDR011 MDR002 MDR011
GPA50003266 + GPA50003607 + GPA50003268 + GPA50003280	Durex PEI Surprise Me óvszercsomag	Hungary	40 (10, 10, 10, 10)	MDR011 MDR011 MDR011 MDR002
GPA50003266 + GPA50003618 + GPA50003662 + GPA5000032	Durex PEI Fun Explosion óvszercsomag	Hungary	40 (10, 10, 10, 10)	MDR011 MDR011 MDR011 MDR002
GPA50003266 + GPA50003607 + GPA50003268 + GPA50003280	Durex Surprise Me	Belgium France Italy Luxembourg Netherlands	40 (10, 10, 10, 10)	MDR011 MDR011 MDR011 MDR002
GPA50003280 + GPA50003266 + GPA50003618 + GPA50003268	Durex Surprise Mix	Italy	40 (10, 10, 10, 10)	MDR002 MDR011 MDR011 MDR011
GPA50003280 + GPA50003266 + GPA50003618 + GPA50003268	Durex surprise mix preservativos	Portugal Spain	40 (10, 10, 10, 10)	MDR002 MDR011 MDR011 MDR011

Appendix 3: Languages accepted in the European Union Member States and other European Countries

Country	Official and National Languages
Austria	German, English
Belgium	Dutch, French, German, English
Bulgaria	Bulgarian
Croatia	Croatian, English
Cyprus	Greek, English
Czech Republic	Czech, Slovak, English
Denmark	Danish, English
Estonia	Estonian, English
Finland	Finnish, Swedish, English
France	French, English
Germany	German, English
Greece	Greek and/or another EU language accepted from the NB
Hungary	Hungarian
Ireland	Irish, English
Iceland	Icelandic, English
Italy	Italian and/or another EU language accepted from the NB
Latvia	Latvian
Lithuania	Lithuanian
Liechtenstein	German, English
Luxembourg	Luxembourgish, French, German and/or another EU language accepted from the NB
Malta	Maltese, English
Netherlands	Dutch, English
Norway	Norwegian, English
Poland	Polish, English
Portugal	Portuguese, English
Romania	Romanian, English
Slovakia	Slovak, English
Slovenia	Slovene
Spain	Spanish
Sweden	Swedish, English and/or another EU language accepted from the NB
Turkey	Turkish

Appendix 4: European Declaration of Conformity Translation

As per Article 19 of MDR (EU) 2017/745, '*Declarations shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.'*

Translated Declaration of Conformities will be presented upon request.

MDR 011 - EU Declaration of Conformity

Final Audit Report 2025-10-03

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