Declaration of Conformity

The EU Declaration of Conformity is under the sole responsibility of the manufacturer.
The devices covered by this present declaration are in conformity with EU Medical device Regulation 2017/745.

Device Identification

Device Name: Feel and Flavoured lubricants

Brand: Durex

File Reference: MDR 031

Issue Number: 1.0

Component Number: See below table

Global Product Name	Formulation code	Date of first CE mark under MDR
Durex Originals H_2O	FRM8312322	31st March 2025
Durex Play Cherry	FRM3091519	31st March 2025
Durex Play Strawberry	FRM3091667	31st March 2025

Basic UDI: 5000158MDR031AW

EMDN Code: U0803

Legal Manufacturer

Name: Reckitt Benckiser Healthcare (UK) Limited

Address: Dansom Lane
Hull
HU8 7DS

Country: United Kingdom

SRN: GB-MF-000035615

Reckitt Benckiser Healthcare (UK) Limited
Dansom Lane
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HU8 7DS
United Kingdom
T: +44 (0)1482 326151 W: Reckitt.com

Authorised Representative:

Name:	RB NL Brands B.V.
Address:	Schiphol Boulevard 207 1118 BH Schiphol
Country:	The Netherlands
SRN:	NL-AR-000006055

Registration Information

Notified Body ID: SGS Belgium NV NB1639

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 description information table above.

Conformity Assessment

Device Classification:	Class IIb, according to Rule 21 (Devices that are composed of substances or of combinations of substances that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body) of Annex VIII of the Medical Device Regulation EU 2017/745
Conformity Assessment Route:	Medical Device Regulation EU 2017/745 - Annex IX and Annex IV
Applicable Legislative Acts:	Refer to Appendix 1 of the Declaration of Conformity

Reckitt Benckiser Healthcare (UK) Limited
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Registered in England, No. 6270876 Registered office at 103-105 Bath Road, Slough, Berkshire, SL1 3UH, United Kingdom

Intended Use

These devices achieve their intended use via a physical mode of action. The intended use of the devices is for the alleviation of vaginal dryness and discomfort

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 EU 2017/745 and conforms to the legislative acts detailed in Appendix 1 of the Declaration of Conformity.

Signature

Name: Lavinia Tompkins

Function: Regulatory Operations Manager

Signature: Lavinia Tompkins

Electronically signed by: Lavinia Tompkins
Reason: I approve this document.
Date: Mar 31, 2025 11:39 GMT+1

Date: 31-Mar-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
MDR EU 2017/745	Medical Device Regulation 2017/745

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 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
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

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
ISO/ TR 24971:2020	Medical Devices – Guidance on the application of ISO 14971
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	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 10993-23:2021	Biological evaluation of medical devices, Tests for irritation
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 10993-11:2018	Biological evaluation of medical devices. Tests for systemic toxicity
BS EN ISO 10993-17:2009	Biological evaluation of medical devices. Establishment of allowable limits for leachable substances
BS EN ISO 14155:2020	Clinical investigation of medical devices for human subjects — Good clinical practice
ASTM D7661-23	Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms
BS EN ISO 20417:2021	Medical Devices –Information supplied by the manufacturer
BS EN 62366-1:2015 + A1:2020	Medical Devices – Part1: Application of usability engineering to medical devices
BS EN ISO 15223-1: 2021	Medical devices. Symbols to be used with information to be supplied by the manufacturer— Part 1: General requirements
ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
ISTA 2A	International Safe Transit Association; Test Procedure-2A
ISTA 6	International Safe Transit Association; Test Procedure 6 – Amazon.com Over Boxing

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	January 2013

	Vigilance system (2019 – Additional guidance)	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
MDCG 2021-25	Regulation (EU) 2017/745 – application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	October 2021
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, Revision 4
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 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	Q&A on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU)	May 2022

Appendix 2: Variants and Pack Sizes

At the time of signing the first version of this European Declaration of Conformity, Feel and Flavoured lubricants are not placed in the EU under MDR EU 2017/745. Variants and pack size will be added in the next revision of this technical file.

Appendix 3: Languages accepted in the EU 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: 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 Declarations of Conformity will be presented upon request.

SIGNATURE PAGE

Document Name: MDR031_EU Declaration of Conformity (DoC)

Document Version: 3.0, LATEST, Approved

Date (UTC)	Event	Signed by	Reason
31-Mar-2025 10:45:58	_complete_task	Tompkins Lavinia	Signing as Approver