



TECHNICAL FILE

PRODUCT NAME:

Family- Thin/Extra Thin Natural Rubber Latex (NRL) Condoms With Silicone or Water-based Lubricant

REF:

MDTF 115

REASON FOR ISSUE:

Refer to cover page

PROJECT NUMBER:

N/A

ISSUE NUMBER:

19

DATE:

October 2021

4. EC Declaration of Conformity

Product identification

Product name:	Thin/Extra Thin natural rubber latex condoms
Brand:	Durex
Reference:	MDTF 115
Issue Number:	19
Component number:	See Appendix 1

Manufacturer

Name:	Reckitt Benckiser Healthcare (UK) Limited
Address:	Dansom Lane, Hull, East Yorkshire, HU8 7DS
Country:	UK

Authorized Representative/Distributor in Europe

Name:	RB NL Brands B.V
Address:	Schiphol Boulevard 207, 1118 BH Schiphol.
Country:	Netherlands

Registration Information

Notified Body ID:	1639
Name:	SGS Belgium NV
Address:	Noorderlaan 87, BE-2030 Antwerpen
Country:	Belgium
CE Certificate No.:	GB19/963047
Date CE marked:	See Appendix 1

CONFIDENTIAL



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PRODUCT NAME: **Family- Thin/Extra Thin Natural Rubber Latex (NRL) Condoms With Silicone or Water-based Lubricant** REF: **MDTF 115**

REASON FOR ISSUE: **Refer to cover page** PROJECT NUMBER: **N/A** ISSUE NUMBER: **19** DATE: **October 2021**

Conformity Assessment

Classification: Medical Device Class IIb Rule: 14
 Route to compliance: Annex II (excluding Section 4.0) of MDD 93/42/EEC Council Directive
 Standard Applied: See Appendix 1

Reckitt Benckiser Healthcare (UK) Limited declares that the product listed is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC and conforms to the standards listed in Appendix 1.

Signatures

Name and function: Andrew Brownhill Regulatory Manager, Intimate Wellness Signature: Date: Option 1

Andrew Brownhill

*Electronically signed by:
 Andrew Brownhill
 Reason: I approve this document.
 Date: Nov 5, 2021 17:09 GMT*

Appendix 1 – Component Numbers

Component Number	Date of First CE Mark
GPA5000006, GPA5000002, GPA5000007, GPA5000001, GPA5000033, GPA5000029, GPA5000034, 3084580, 3084577, 3071767, 3115435, 3085108, 3115434, 3084583, 3115428, 3085098, 3115391, 3147693, CS000345, CS000351, CS000545, CS000171, CS000378, 3126277, 8003769, 8003772, 8055271	19-Mar-2010
8198646, 3121223, 8164344, 3121222, 3116399	8-Sep-2015
3085096, 3115427, 3085105, 3115425	13-Jan-2017
3098765	8-Apr-2019
3099490, 3099492, 3159391, 3159414	7-Jun-2019
3099715, 3159413, GPA50000871	11-Sep-2020
GPA50003119, GPA50003307, GPA50003275, GPA50003276, GPA50003271, GPA50003272, GPA50000423	21-Oct-2020
GPA50003607, GPA50003662, 3173762, 3155197, 3184301, 3155080	25-May-2021
3195620, 3209215, 3155071, 3155088, 3147915, 3155090, 3155086, 3155075, 3155085, 3155077, 3155084, 3155081, 3184311, 3184310, 3184303, 3156158, 3184313, 3156159,	05-Nov-2021

* Refer to the signatory date of this declaration of conformity.







5. EC Declaration of Conformity MDTF 115_Thin - Extra thin NRL condoms with silicone or water based lubricant (7)

Final Audit Report

2021-11-05

Created:	2021-11-05
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"5. EC Declaration of Conformity MDTF 115_Thin - Extra thin NRL condoms with silicone or water based lubricant (7)" History

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