

4. EC Declaration of Conformity

Product identification

Product name: Thin/Extra Thin natural rubber latex condoms
Brand: Durex
Reference: MDTF 115
Issue Number: 23
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

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:
Mark Ainsworth
Senior Manager, Medical Device, Regulatory Lead

Signature:

Date:


*Electronically signed
by: Mark Ainsworth
Reason: I approve
this document.
Date: Dec 12, 2022
13:05 GMT*

12-Dec-2022

CONFIDENTIAL

Appendix 1 – Component Numbers

Component Number	Date of First CE Mark
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
GPA5000006, GPA5000002, GPA5000007, GPA5000001, GPA5000033, GPA5000029, GPA5000034	12-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
GPA50014642	24-Jun-2022
GPA50008509, GPA50008518, GPA50008519, GPA50008523, GPA50008524, GPA50008533, GPA50008536, GPA50008538, GPA50008539, GPA50008548, GPA50008551, GPA50008553, GPA50008555, GPA50008556, GPA50008558, GPA50008559, GPA50008570, GPA50008575, GPA50008576, GPA50008579, GPA50008581, GPA50008583, GPA50008584, GPA50008588, GPA50008589, GPA50008596, GPA50008609, GPA50006449, GPA50003618, GPA50020502, GPA50020503	3-Aug-22
GPA50033994, GPA50033998, GPA50019154, GPA50020217	12-Dec-2022






EC Declaration of Conformity MDTF 115_Thin _ Extra thin NRL condoms with silicone or water based lubricant

Final Audit Report

2022-12-12

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"EC Declaration of Conformity MDTF 115_Thin _ Extra thin NRL condoms with silicone or water based lubricant" History

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