

4. EC Declaration of Conformity

Product identification

Product name: Thin/Extra Thin natural rubber latex condoms  
Brand: Durex  
Reference: MDTF 115  
Issue Number: 27  
Component number: See Appendix 1

Manufacturer

Name: Reckitt Benckiser Healthcare (UK) Limited  
Address: Dansom Lane, Hull, 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, 2030 Antwerp  
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 List of Applied Harmonized Standards.

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 the List of Applied Harmonised Standards.

Signatures

Name and function:  
Mark Ainsworth  
Senior Manager, Medical Device, Regulatory Lead

Signature:



Electronically signed by: Mark Ainsworth  
Reason: I approve this document.  
Date: Sep 19, 2024 15:48 GMT+1

Date:

19-Sep-2024

Appendix 1 – Component Numbers

| Component Number                                                                                                                                                                                                                                                                                                                                                                                                  | Date of First CE Mark |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| 3084580, 3084577, 3071767, 3115435, 3115434, 3084583, 3115428, , 3115391, 3147693, CS000345, CS000351, CS000171, CS000378, 3126277                                                                                                                                                                                                                                                                                | 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           |
| 3155071, 3147915, 3155090, 3155075, 3155085, 3155077, 3155084, 3155081, 3184311, 3184310, 3184303, 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-22             |
| GPA50022328, GPA50022329                                                                                                                                                                                                                                                                                                                                                                                          | 16-Aug-23             |

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

Final Audit Report

2024-09-19

|                 |                                                         |
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