



# TECHNICAL FILE

PRODUCT NAME:

**Family-Transparent, Standard Natural Rubber Latex Condoms with Silicone Lubricant**

REF:

**MDTF 139**

REASON FOR ISSUE:

**Refer to cover page**

PROJECT NUMBER:

**N/A**

ISSUE NUMBER:

**17**

DATE:

**October 2021**

## 4. EC Declaration of Conformity

### Product identification

Product name: Transparent, standard natural rubber latex condoms  
Brand: Durex  
Reference: MDTF 139  
Issue Number: 17  
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  
Date originally 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:  
Andrew Brownhill,  
Regulatory Manager, Intimate Wellness

Signature:

*Andrew Brownhill*

Date: Option 1

Electronically  
signed by:  
Andrew  
Brownhill  
Reason: I  
approve this  
document.  
Date: Nov 5,  
2021 17:08  
GMT

**CONFIDENTIAL**



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### Appendix 1 – Component Numbers

| Component Number   | Date of First CE Mark |
|--|-----------------------|
| CS000321, CS000354, CS000358, CS000478, CS000483, CS000510, CS000560, 8046858, 8296475   | 19-Mar-2010           |
| 3084776, 3084578, 3084783, CS000198/3084777, CS000325/3085110, 3085112, GPA5000003, GPA5000008, GPA5000009, GPA5000025, GPA5000026, GPA5000016, GPA5000014, GPA5000023, GPA5000031, GPA5000017 | 8-Apr-2019            |
| 3115418, 3115420, 3115424, 3115429, 3118925  | 27-Nov-2019           |
| 3115421  | 8-Sep-2020            |
| GPA50003273, GPA50003277, GPA50003278, GPA50003269, GPA50003270, GPA50003265, GPA50003281, GPA50003309, GPA50003312, GPA50003266.  | 25-May-2021           |
| GPA50004747, 3155079, 3155083, 3156161, 3156174, 3155087, 3155062  | 05-Nov-2021           |

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

# EC Declaration of Conformity\_MDTF 139 Technical File Standard NRL Condoms with Silicone Lubricant

Final Audit Report

2021-11-05

|                 |   |
|-----------------|---|
| Created:        | 2021-11-05  |
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