



TECHNICAL FILE

PRODUCT NAME:	Synthetic Polyisoprene Condom with Silicone Lubricant			REF:	MDTF 172
REASON FOR ISSUE:	PROJECT NUMBER:	ISSUE NUMBER:	DATE:		
Refer to cover page	N/A	12	April 2021		

4. EC Declaration of Conformity

Product identification

Product name:	Durex easy on, standard, transparent synthetic polyisoprene condom with silicone lubricant
Brand:	Durex
Reference:	MDTF 172
Issue Number:	12
Component Number:	GPA5000035, GPA5000036, GPA5000041

Manufacturer

Name:	Reckitt Benckiser Healthcare (UK) Ltd
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, BE-2030 Antwerpen.
Country:	Belgium
CE Certificate No.:	GB19/963047
Date CE marked:	8 th April 2019

Originally CE Marked 24th July 2010 under SGS UK, 0120. CE Certificate GB99/50557.01.

Conformity Assessment

Device Classification:	Class:	IIb	Rule:	14
Route to compliance:	Annex II (excluding Section 4) of MDD 93/42/EEC Council Directive			
Standard Applied:	See Appendix 1			

Reckitt Benckiser Healthcare (UK) Ltd 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

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DATE:

April 2021

Name and function:

Samantha Neilson,
Head of SWB Global Regulatory

Signature:

Date: 25-May-2021 | 10:04 PDT

DocuSigned by:

Samantha Neilson



Signer Name: Samantha Neilson
Signing Reason: I approve this document
Signing Time: 25-May-2021 | 10:04 PDT

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