

TECHNICAL FILE

PRODUCT NAME:
DUREX SENSATION LUBRICANT FAMILY FILE

REF:
MDTF 199

REASON FOR ISSUE: PROJECT NUMBER: ISSUE NUMBER:
Refer to cover page N/A 12

DATE:
Sep 2021

4. EC Declaration of Conformity

Product identification

Product name: Sensation lubricants
Brand: Durex
Reference: MDTF 199
Issue Number: 12
Component number: *8032226, **8110486, **8110495.

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, BE-2030 Antwerpen.
Country: Belgium

CE Certificate No.: GB19/963047

Date CE marked: 8th April 2019

Originally CE Marked *14th December 2012 and **16th October 2014 under SGS UK, 0120. CE Certificate number GB99/50557.

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Conformity Assessment

Classification: Medical Device Class IIa Rule: 5
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 as amended and conforms to the standards listed in Appendix 1.

Signatures

Name and function:
Samantha Neilson,
Head of Global Regulatory -SWB

Signature:
Samantha Neilson

Date:
23-Sep-2021

Electronically signed by:
Samantha Neilson
Reason: I approve this document
Date: Sep 23, 2021 08:30
GMT+1

Approved

10-Nov-2021 13:31:26
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MDTF 199_Sensation_Declaration of Conformity

Final Audit Report

2021-09-23

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Date (GMT)	Signed by	Reason
23-Sep-2021 08:21:33	Hussey Hannah (HHussey)	Signing as Approver

Approved