

Declaration of Conformity

Product identification

Product name: KY Jelly (sterile)
Brand: KY/K-Y/Durex K-Y/ KY Durex/ K-Y Durex/ Durex
Reference: MDTF 198
Issue Number: 06
Component number: 8203148

Manufacturer

Name: RB Healthcare (UK) Ltd
Address: Dansom Lane, Hull, HU8 7DS
Country: United Kingdom

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 22nd February 2016 under SGS UK, 0120. CE Certificate number GB99/50557.01.

Classification: Class: IIa Rule: 5
Route to compliance: Annex II (Excluding section 4) of MDD 93/42/EEC Council Directive (as amended)
Standard Applied: MDTF 198

Reckitt Benckiser Healthcare (UK) declares that the above-mentioned product is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended and conforms to the standards listed in MDTF 198.

Signatures

Name and function:
Hannah Hussey
Global Regulatory Manager – Intimate
Wellness Compliance Manager

Signature:



Electronically signed by: Hannah
Hussey
Reason: I approve this document.
Date: Sep 9, 2022 07:15 GMT+1

Date:

09-Sep-2022







02 MDTF 198_Sterile_Declaration of Conformity

Final Audit Report

2022-09-09

Created:	2022-09-08
By:	Maryam Roostan (Maryam.Roostan@reckitt.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAANovnmklyY3ONhmtNqc1fE4_TMsJoHd4g

"02 MDTF 198_Sterile_Declaration of Conformity" History

-  Document created by Maryam Roostan (Maryam.Roostan@reckitt.com)
2022-09-08 - 20:07:40 GMT
-  Document emailed to Hannah Hussey (Hannah.Hussey@reckitt.com) for signature
2022-09-08 - 20:08:30 GMT
-  Email viewed by Hannah Hussey (Hannah.Hussey@reckitt.com)
2022-09-09 - 06:09:28 GMT
-  Hannah Hussey (Hannah.Hussey@reckitt.com) verified identity with Adobe Acrobat Sign authentication
2022-09-09 - 06:15:48 GMT
-  Document e-signed by Hannah Hussey (Hannah.Hussey@reckitt.com)
Signing reason: I approve this document.
Signature Date: 2022-09-09 - 06:15:48 GMT - Time Source: server
-  Agreement completed.
2022-09-09 - 06:15:48 GMT



HEALTH ▾ HYGIENE ▾ HOME

SIGNATURE PAGE

Document Name: MDTF 198_Sterile_Declaration of Conformity

Document Version: 11.0 Approved CURRENT

Date (GMT)	Signed by	Reason
14-Sep-2022 12:14:05	Brookes Rebecca (RBrookes)	Signing as Approver

Approved