



SIGNATURE PAGE

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2.3.3 Declaration of Conformity

Product identification

Product name or Device name KY Jelly (sterile)
Brand: KY/K-Y/ Durex KY/ Durex K-Y/ KY Durex/ K-Y Durex/
Durex
Component Number: 8203148 (Doppel) & 8172269 (Janssen-Cilag)

Manufacturer

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

Authorized Representative/Distributor in Europe

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

Registration Information

Notified Body ID: 0120
CE Certificate No.: GB99/50557.01
Date CE marked: 22nd February 2016


Conformity Assessment

Device Classification: Class: IIa Rule: 5
Route to compliance: Annex II (Excluding section 4) of MDD 93/42/EEC Council
Directive (as amended)
Standards Applied: MDTF 198, section 2.3.4

RB Healthcare (UK) Ltd 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 MDTF 198, section 2.3.4.

Signatures

Name and function:
Mark Ainsworth
Global Regulatory Manager Health

Signature:  Date: 31st MARCH 2017