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