

SIONBIOTEXT

DECLARATION OF CONFORMITY

We, Sion Biotext Medical Ltd.
Name and address of manufacturer: Ha'goshrim 1222500, Upper Galilee, Israel

Declare under our sole responsibility that the products:

Name	Lubricating Jelly
The medical device	Sterile Lubricating Jelly and CerviLube Lubricating Jelly – Carbomer, Paraben & CHG free in different packages and sizes (see TF-4)
Type	
Lot	Starting Lot No. 121012, 20112006

Classified in Class IIa, with accordance to Rule number 5 meets all applicable requirements of the Directive 93/42/EEC (2007/47/EEC) Annex IX.

The Technical Construction File is maintained at: Ha'Goshrim 1222500, Upper Galilee, Israel

Name, address and identification number of MDC Medical Device Certification GmbH Kriegerstraße 6, D-70191 Stuttgart, Germany ID Number: 0483.
Notified body:


Conformity assessment procedure: Conformity assessment was performed according to Annex V and Annex VII of the 93/42/EEC (2007/47/EEC) Directive.

European Representative Information
Theo Manufacturing B.V.
Capucijnenstraat 71, 6211 RP Maastricht, P.O. Box 370,
6200 AJ Maastricht, The Netherlands
Email address: info@theomanufacturing.com
Tel: +31 (0)43 325 1773

Place, date
Sion Biotext Medical Ltd.
Ha'goshrim
01.01.2018



Ortal Cohen, RA Manager



Michal Libraider Tarshish, VP QA/RA