## **EC** Certificate

#### mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

# Sion Biotext Medical Ltd. 3 Ha'Eshel St., Sapirim Industrial Park Sderot, 8701002 Israel

for the scope

Sterile Lubricating Jelly, Sterile and Non-Sterile CerviLube Lubricating Jelly, Sterile Dressings and Absorption Products

has introduced and applies a

### **Quality System**

for the manufacture of the products concerned and carries out a final inspection as specified in Annex V, Section 3.

The mdc audit has proven that this quality system meets all requirements according to

## Annex V – Section 3 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex V, Section 4.

 Valid from
 2020-02-25

 Valid until
 2024-05-26

 Registration no.
 D1103900027

 Report no.
 P19-01245-155344

 Stuttgart
 2020-02-25

Head of Certification Body





Internet: http://www.mdc-ce.de