

# 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

**Surgical Drapes & Equipment Covers and Kits,  
Medical Dressing Products, Surgical Prep Kits and Packs**

has introduced and applies a

## Quality System

for the aspects of manufacture concerned with securing and  
maintaining sterile conditions 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	2019-12-10
Valid until	2024-05-26
Registration no.	D1103900026
Report no.	P19-01245-155348
Stuttgart	2019-12-10



Head of Certification Body

