

Supplement to the EC Design Examination Certificate

No. 4004.11.14/0 dated 2009-09-09

Customer no.	4004
Manufacturer	Bohus BioTech AB
Certification base	MDD 93/42/EEC, Annex II, Section 4
Product(s)	BBTvisc™ (viscoelastic devices based on hyaluronic acid for use in ophthalmic surgery)
Intended change	Addition of a second cannula supplier for sterile cannulae (Sterimedix Ltd.)
Review report no.	4004.11/2011-02-18

The intended change is in compliance with the requirements of the Directive 93/42/EEC.

This supplement is valid only in conjunction with the aforementioned EC Design Examination Certificate.

The aforementioned EC Design Examination Certificate is valid only in conjunction with this supplement.

This supplement is valid until: 2014-09-09
Supplement registration no: 4004.11.14/0-01
Stuttgart 2011-02-18



Head of
Certification Body



mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: <http://www.mdc-ce.de>