

EC Certificate



Production Quality Assurance

No. CE 518678

Issued to:

Medical Concepts Development, Inc.
2500 Ventura Drive
Woodbury
Minnesota
55125
USA

In respect of:

The manufacture of sterile single-use surgical drapes and bags for temporary storage or isolation

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

A handwritten signature in black ink, appearing to read 'Alastair Trivett', written over a horizontal line.

Alastair Trivett, Managing Director, BSI Product Services – Global

First Issued: 18 Feb 2008

Date: 18 Feb 2008

Expiration Date: 17 Feb 2013

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive.

This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate unless specifically agreed with BSI.

EC Certificate

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor	Service(s) supplied
Medical Concepts Development, Inc 835 Hale Avenue Oakdale Minnesota USA 55128	Distribution Packaging
Steris Isomedix Services, Inc. 1160 Northpoint Boulevard Waukegan Illinois 60085 USA	ETO Sterilization

History of Quality Assurance Certificate

Certificate No: CE 518678
Issue Date: 18 Feb 2008
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Date	Customer Reference	Action
18 February 2008	7034533	First issue