

bsi.



Certificate

Production Quality Assurance

No. CE 01943



Issued to:

**Medical Indicators Inc
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA**

In respect of:

Those aspects of Annex V relating to metrology and securing and maintaining sterility in the manufacture of Phase-change type thermometers

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 BSI, a Notified Body for the above Directive (Notified Body Number 0086):

Gary Fenton, Global Assurance Director

First Issued: **12 Jun 1998**

Date: **1 May 2013**

Expiration Date: **14 Feb 2018**

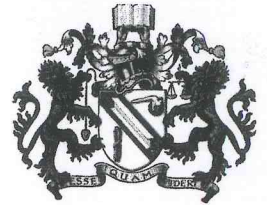
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Conditions of Approval

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.

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List of Significant Subcontractors

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

Certificate No. **CE 01943**
Date: **1 May 2013**
Issued to: **Medical Indicators Inc**
Hamilton
New Jersey
USA

Subcontractor

Service(s) supplied

Advena Ltd.
Pure Offices
Plato Close
Warwick
CV34 6WE
United Kingdom

EU Representative

Sterigenics US, LLC
108 Lake Denmark Road
Rockaway
New Jersey
07866
USA

Gamma Sterilization



History of Quality Assurance Certificate

Certificate No: **CE 01943**
Date **1 May 2013**
Issued to: **Medical Indicators Inc**
Hamilton
New Jersey
USA

Date	Reference Number	Action
12 June 1998		Original issue.
10 June 1999		Change of address and reissue of certificate
21 March 2003		Change of address and reissue of certificate
14 February 2008	7008514	Certificate Renewal and correction to history page
04 March 2013	7942928	Certificate Renewal Addition of subcontractor, 'Advena Ltd, 33 Bridge Street, Hereford, HR4 9DQ' for EU Rep Address change from '1589 Reed Road, Pennington, New Jersey, USA' to '16 Thomas J. Rhodes Industrial Drive, Hamilton, New Jersey, USA'
01 May 2013	7985893	Extension to scope to include 'securing and maintaining sterility'. Addition of Sterigenics as significant subcontractor, change of address of EU Rep to Plato Close, Warwick location