

# EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

**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 of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Albert Roossien, Regulatory Lead

First Issued: **1998-06-12**

Date: **2019-02-07**

Expiry Date: **2023-02-14**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. 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.

This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

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## List of Significant Subcontractors

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

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**Subcontractor:**

**Service(s) supplied**

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Advena Ltd  
Pure Offices  
Plato Close  
Warwickshire  
CV34 6 WE  
United Kingdom

**EU Representative**

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

**Gamma Sterilization**

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# EC Certificate - Production Quality Assurance Certificate History

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## Certificate History

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
09 February 2018	8850099	Renewal
Current	7781689	Traceable to NB 0086.

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