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):

Gary E Slack, Senior Vice President Medical Devices

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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Supplementary Information to CE 01943

Issued To:

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Device code	Device name	Intended purpose per IFU
Class Is, Im		
MD 0104	Phase change type thermometer	---

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

List of Significant Subcontractors

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

Certificate No:	**CE 01943**
Date:	**2019-02-07**
Issued To:	**Medical Indicators Inc** **16 Thomas J. Rhodes Industrial Drive** **Hamilton** **New Jersey** **08619** **USA**

Subcontractor:	**Service(s) supplied**
Advena Limited Tower Business Centre, 2nd Flr Tower Street Swatar BKR 4013 Malta	**EU Representative**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 01943**

Date: **2019-02-07**

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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
07 February 2019	7781689	Traceable to NB 0086.

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Date	Reference Number	Action
07 February 2019	3391689	Change of EU rep. Addition of device table.
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
23 February 2022	3617981	Scope reduction to Those aspects of Annex V relating to metrology in the manufacture of Phase-change type thermometers. Removal of the sterile device Tempadot Sterile Clinical thermometer (Class Is,m). Removal of Critical subcontractor Sterigenics US, LLC.

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.
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Inspiring trust for a more resilient world.

23 February 2022

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

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 01943	93/42/EEC Annex V	3617981	Reduce the certificate scope from "Those aspects of Annex V relating to metrology and securing and maintaining sterility in the manufacture of Phase-change type thermometers" to "Those aspects of Annex V relating to metrology in the manufacture of Phase-change type thermometers". Removal of the sterile device Tempadot Sterile Clinical thermometer (Class Is,m). Removal of Critical subcontractor Sterigenics US, LLC, 108 Lake Denmark Road, Rockaway, New Jersey 07866, USA.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
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SUSTAINABLE DEVELOPMENT GOALS