

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

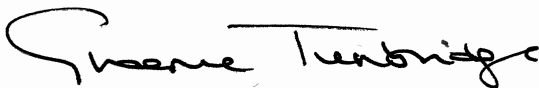
No. UKCA 761223
Issued To: Medical Indicators Inc
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA

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 Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2021-12-03**

Date: **2022-04-28**

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

...making excellence a habit.™

Page 1 of 2

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

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

Approved Body Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP, UK. Tel: + 44 845 080 9000

Corporate Contact: BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London, W4 4AL, UK.

A member of BSI Group of Companies.

UKCA Certificate - Production Quality Assurance

Supplementary Information to UKCA 761223

Issued To:

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

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

First Issued: **2021-12-03**

Date: **2022-04-28**

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

...making excellence a habit.™

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

List of Critical Subcontractors and Crucial Suppliers

Recognised as being involved in services related to the products covered by:

Certificate No: **UKCA 761223**
Date: **2022-04-28**
Issued To: **Medical Indicators Inc**
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA

Subcontractor:

Service(s) supplied

Advena Limited
Pure Offices
Plato Close
Warwick
CV34 6WE
United Kingdom

UK Responsible Person

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

Radiation (Gamma Sterilization)

...making excellence a habit.™

UKCA Certificate - Production Quality Assurance

Certificate History

Certificate No: **UKCA 761223**
 Date: **2022-04-28**
 Issued To: **Medical Indicators Inc**
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA

Date	Reference Number	Action
03 December 2021	3576377	First issue; Traceable to CE 01943.
23 February 2022	3617431	Removal of the sterile device Tempadot Sterile Clinical thermometer (Class Is,m) and of Critical subcontractor Sterigenics US, LLC. Reduce the certificate scope to "Those aspects of Annex V relating to metrology in the manufacture of Phase-change type thermometers".
Current	3662306	Add the sterile device Tempadot Sterile Clinical thermometer (Class Is) and add the Critical subcontractor Sterigenics US, LLC. Extend the certificate scope to Those aspects of Annex V relating to metrology and securing and maintaining sterility in the manufacture of phase-change type thermometers.

...making excellence a habit.™