

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]

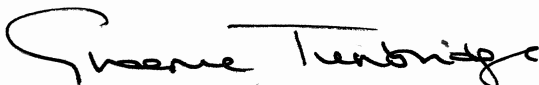
No. UKCA 761223
Issued To: **Medical Indicators Inc**
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA

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: **2023-05-02**

Expiry Date: **2028-02-14**

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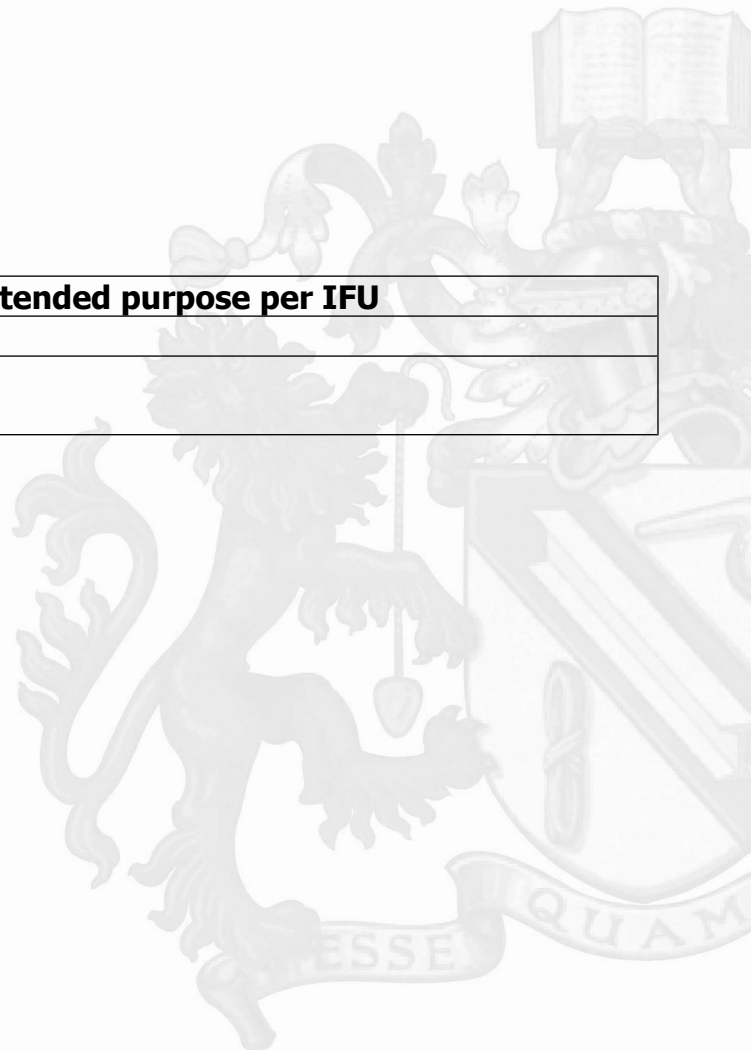
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Supplementary Information to UKCA 761223

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



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Certificate History

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Date	Reference Number	Action
2021-12-03	3576377	First issue; Traceable to CE 01943.
2022-02-23	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".
2022-04-28	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.
Current	3892105	Certificate Renewal Administrative update to previous date formatting

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