EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 761220 R000

Manufacturer: Medical Indicators Inc

Address:
16 Thomas J. Rhodes Industrial Drive
Hamilton
New Jersey
08619
USA

Single Registration Number: US-MF-000018094

EU Authorised Representative: Advena Limited

Address:
Tower Business Centre, 2nd Flr
Tower Street
Swatar
BKR 4013
Malta

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

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

Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-03-23**

Current Issue Date: **2023-03-23**

Starting Validity Date: **2023-03-23**

Expiry Date: **2028-03-22**

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Sterile phase-change type thermometers	Class Is, Class Im,
Non-Sterile phase-change type thermometers	Class Im
For Class Is devices, the Notified Body conformity assessment is limited to the aspects relating to establishing, securing and maintaining sterile conditions. For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.	

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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	3576420	Issued

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
A Member of the BSI Group of Companies.