

EC Certification



FULL QUALITY ASSURANCE SYSTEM
Directive 93/42/EEC for Medical Devices, Annex II excluding (4)

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the UK national legislation to which the undersigned is subjected, transposing Annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive, and the result entitles the organization to use the CE 0473 marking on those products listed below.

INDITHERM PLC

Inditherm House, Houndhill Park, Bolton Road, Wath-upon-Dearne, Rotherham S63 7LG

Heated blankets and mattresses and heating control units
As per attached schedule

Certificate Number: 341 CE
Initial Certification Date: 06 January 1999
Certificate Effective Date: 12 September 2014
Certificate Expiry Date: 05 January 2019

Brian Johnson
AMTAC Certification Services Limited, Milton Keynes, UK
This certificate is the property of AMTAC Certification Services Ltd



In the issuance of this certificate, Intertek assumes no liability to any party other than to the Client, and then only in accordance with the agreed upon Certification Agreement. This certificate's validity is subject to the organization maintaining their system in accordance with Intertek's requirements for systems certification. Validity may be confirmed via email at certificate.validation@intertek.com or by scanning the code to the right with a smartphone. This Certificate is for the exclusive use of AMTAC's client and is provided pursuant to the agreement between AMTAC and its Client. AMTAC's responsibility and liability are limited to the terms and conditions of the agreement. AMTAC assumes no liability to any party, other than to the Client in accordance with the agreement, for any loss, expense or damage occasioned by the use of this Certificate. Only the Client is authorized to permit copying or distribution of this Certificate. Any use of the AMTAC name or one of its marks for the sale or advertisement of the tested material, product or service must first be approved in writing by AMTAC.

The certificate remains the property of Intertek, to whom it must be returned upon request.

The certification is subject to the organization maintaining their system in compliance with the regulations stated in this certificate, allowing regular assessments and following the contracted requirements of the Notified Body. AMTAC Certification Services Limited is a Notified Body according to Directive 93/42/EEC for medical devices, with identification number 0473.

PRODUCT SCHEDULE FOR CERTIFICATE 341 CE INDITHERM PLC



Intertek

PRODUCT and MODELS

CONTROL UNITS

MECU1
CCU1, CCU 200, CCU 201, CCU 202, CCU 203, CCU 204 and CCU 205
CRU1
TCU1, TCU 200, TCU 201, TCU 202, TCU 203, TCU 204 and TCU 205
MCU200, MCU 201, MCU 202 MCU 203, MCU 204 and MCU 205
FCU200-202

OPERATING THEATRE MATTRESSES & BLANKETS

OTM1
OTM1 - N
OTM2
OMT2 - N
OTM3
OTM-SPE
PTM1
GTM1
GTM1 - N
OTB1
OTB2
OTB-SPE
OTB
FHP001

RECOVERY BLANKETS

RB1
RB2
RB-SPE

EMERGENCY MATTRESSES

TTM1
TTM2
TTM3
TTM-SPE

COSYTHERM MATTRESSES & BLANKETS

NEONATAL BLANKET NCB1 NCB-SPE

NEONATAL MATTRESSES

NCM1
NCM2
NCM3
NCM4
NCM5
NCM6
NCM7
NCM8
NCM-SPE

Initial Certification Date: 06 January 1999
Certificate Effective Date: 12 September 2014



Brian Johnson ~ Authorized Signatory

