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.

MENNEN MEDICAL LTD

6 Ha-Kishon St., Yavne 8122017, Israel

Multiparameter patient monitors
Secondary display central nurse station
Computerized laboratory, Electrophysiological measurement system
As per the attached schedule

Certificate Number: 524-01 CE

Initial Certification Date: 06 February 2002
Certificate Effective Date: 06 February 2017
Certificate Expiry Date: 05 February 2022

Barry A. Fitch
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 524-01 CE MENNEN MEDICAL



Horizon 9000 WS Cathlab with PFE/CFE – Haemodynamic Monitoring System
Horizon SE with PFE/CFE – Haemodynamic Monitoring System
Horizon XVu – Haemodynamic Monitoring System
Horizon 9000SE-compact/Horizon compact
Horizon Angio
Monitor - Cathlab
EMS and EMS XL – Electrophysiology Measurement System
EP Combo System

Dual BP, CO & Two Temperature **Dual BP Dual Temperature** Cardiac Output **NIBP** ETCO₂ Duet – Mainstream & Sidestream ETCO₂ – Mainstream ETCO₂ - Microstream SPO₂ Universal Interface Modules (UIM) – Uniport & Multiport **Envoy Patient Monitor with Remote Viewing** Envoy Patient Monitor with CRT or Flat Display Screen(s) Envoy SPO₂ Module (Masimo) **Envoy 12 Lead Telemetry Module Envoy BIS module EEG Module for Envoy Patient Monitor** Spirometry Module of Envoy Patient Monitor

Ensemble Central Nurse Station
Enguard Remote Monitor/Workstation
Entour Portable Monitor
Enscribe Recorder
Horizon 1100 Patient Monitor
Horizon XL & XL/S Patient Monitor
Horizon 5170/5180 Central Station
Mercury Portable Monitor

VitaLogik Patient Monitor series – BIS interface

Initial Certification Date: 06 February 2002 Certificate Effective Date: 06 February 2017

Multilead ECG/Resp 12 Lead ECG/Resp

Bonny A Joll

PRODUCT SCHEDULE FOR CERTIFICATE 524-01 CE MENNEN MEDICAL



- PHASEIN IRMA
- ANDROS 4800 (Anaesthesia gas and agents monitoring systems)
- Drager Evita (Ventilator)

Criticool Pro

EP-XVU Electrophysiology measurement system

CerebraLogik (Model # 6811380X0)

Menntor X7



Initial Certification Date: 06 February 2002 Certificate Effective Date: 06 February 2017

Barry A. Fitch ~ Authorized Signatory