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

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

Multilead ECG/Resp
12 Lead ECG/Resp
Dual BP, CO & Two Temperature
Dual BP
Dual Temperature
Cardiac Output
NIBP
$ETCO_2$ Duet – Mainstream & Sidestream
$ETCO_2$ – Mainstream
$ETCO_2$ - Microstream
SPO_2
Universal Interface Modules (UIM) – Uniport & Multiport
Envoy Patient Monitor with Remote Viewing
Envoy Patient Monitor with CRT or Flat Display Screen(s)
Envoy SPO_2 Module (Masimo)
Envoy 12 Lead Telemetry Module
Envoy BIS module
EEG Module for Envoy Patient Monitor
Spirometry Module of Envoy Patient Monitor
VitaLogik Patient Monitor series – BIS interface

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

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

Barry A. Fitch ~ Authorized Signatory

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