

-Declaration of Conformity-

Micrel Medical Devices S.A.
Ithakis 4
Pallini GR 15351
GREECE

Declares that the medical device MICROPUMP MP-100 and its variants MP-Daily, MP-Mlh, MP-101, Thalapump20 ambulatory infusion syringe driver has been classified as Class IIb (Annex IX rule 11) and is in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as well as is in conformity with standards listed below.

From IEC 60601-2-24:1998 – Medical electrical equipment, Part 2-24: Particular requirements for the safety of infusion pumps and controllers. Only sub-clause 54.101 “syringe fitting” has not been implemented

Different risk control measures, similar to the mitigation measures used by predicated devices have been taken to maintain the siphoning risk out of the A.L.A.R.P. zone, according to “Application of Risk Management to Medical Devices” Standard ISO14971:2000

Applicable Standards

EN 60601-1 : 1990	Medical Electrical Equipment Part 1: General Requirements for Safety
EN 60601-2-24:1998	Medical Electrical Equipment, Part2: Special requirements for safety of infusion pumps and controllers.
EN 60601-1-2 : 2001	Medical Electrical Equipment Part 1: General requirements for Safety. Electromagnetic compatibility
ISO 14971:2000	Application of Risk Management to Medical Devices

Test Protocols: MIKES Product Service (TUV) EMC Tests No. E23633-00-00 WB
MIKES Product Service (TUV) Leakage Tests No. E23633-00-00 WB

It is CE Marked under the supervision of Notified Body Number 0120 SGS United Kingdom Ltd Systems & Services Certifications Unit 202B Worle Parkway BS22 6WA Weston Super Mare United Kingdom and that we fulfil the obligations imposed by the quality system approved.

Place and date of issue Name and signature of the Quality and Regulatory Affairs Director

PALLINI 4 February 2008

Aspasia Karpeti

