marp electronic

DECLARATION OF CONFORMITY

Company: Z.E.M. MARP Electronic Sp. z o.o.
ul. Pachonskiego 9
31-223 Kraków
Poland

We declare under our sole responsibility that

the medical device: D56A SERIES MAGNETIC FIELD THERAPY DEVICES

models: MAGNOTER D56A, MAGNOTER D56A BL

with laser applicators: LAI-41, LAI-71, LAC-50, LAC-52, LAC-102, LAC-202, LAC-402

of class: IIb, rule 9 according to Annex IX of 93/42/EEC directive

covered by the Technical Files rev. 3, dated 03.2006, meets all provisions of the directive 93/42/EEC which apply to it.

Conformity assessment procedure:

Annex II.3 of 93/42/EEC directive

Harmonised standards:

- EN 60601-1:1990 + A1:1993 + A2:1995 + A13:1996 Medical electrical equipment - Part 1: General requirements for safety
- EN 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
- EN 60601-1-4:1996 + A1:1999 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems
- EN 60601-2-22:1996 Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment

Notified Body: TÜV Rheinland Product Safety GmbH (No 0197)

CE
0197

Issue: 6
Place: Kraków
Date: 2007-04-26

Signature: .....