144492-14-05-15

EC CERTIFICATE

Full Quality Assurance System

Directive 93/42/EEC on Medical devices, Annex II excluding (4)

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering (NB 2409) certifies that the following manufacturer's quality management system concerning to the listed devices and device categories meets the requirements of the related requirements of the directive.

Name of the manufacturer:

MEDICOR Elektronika Zrt.

Headquarters: **1097 Budapest, Illatos út 9. HUNGARY**

Scope:

Electronical medical devices

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Closed neonatal incubator family	BABYLIFE®	Treatment of newborns and prematured infants	BLF-2001 BLF-2001B	II.b
Neonatal warming and resuscitation table family	BABYLIFE®	For emergency treatment of newborns	BLR-2100 BLR-2100A	II.b
Blue light lamp family	BABYLIFE®	Treatment, prevention of hyperbilirubinaemia	KLA-145 KLA-145M	II.a
Digital sphygmomanometers	MEDICOR®	Blood pressure and pulse measurement	SE-2000 SE-4000 SE-7000	II.a
TENS devices	MEDICOR®	Nerve and muscle stimulation, pain relief	SE-30 SE-33 SE-35	II.a

This certificate is valid only in case of successfully conducted annual surveillance audits.

ID number of the related audit report: 78-CE-140303

CE Certiso
Orvos- és Kórháztechnikai
Ellenőrző és Tanúsító Kft.
H-2040 Budaörs, Gyár u. 2.
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Valter PAPP, Dr.
General Manager

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