144886-19-05-20

EC CERTIFICATE

Full Quality Assurance System

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

CE Certiso Ltd. (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:

Neonatal electronic medical devices

The certificate covers the following devices:

Description of the device	Type	Intended use	Model	Risk class
Closed neonatal incubator	BABYLIFE® BLF-2001	Treatment of newborns and prematured infants	BLF-2001G	IIb
Neonatal transport incubator	BABYLIFE® BLF-2001	Treatment and transport of newborns and prematured infants	BLF-2001T	IIb
Neonatal warming and resuscitation table	BABYLIFE® BLR-2100	For emergency treatment of newborns	BLR-2100A	IIb
Blue light lamp	BABYLIFE® KLA-145	Treatment, prevention of hyperbilirubinaemia	KLA-145L	IIa

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

ID number of the related audit report: 78-CE-190311

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First issued: 20 May 2019
Start date of certified status: 20 May 2019

Expires:
19 May 2024

CE Certiso
Orvos- és Kórháztechnikai Ellenőrző és Tanúsító Kft.
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