MEDICOR

BUSINESS Superbrands™

ISO 9001 ISO 13485

MEDICOR ELEKTRONIKA

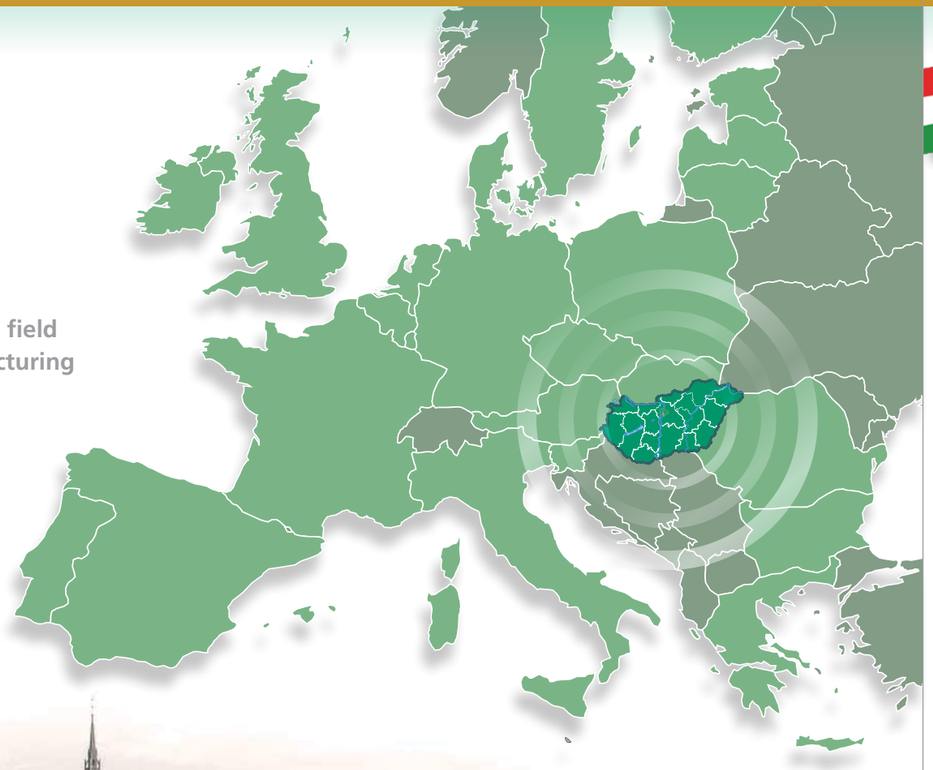
BABYLIFE®

MEDICOR | AUTHENTIC EUROPEAN MANUFACTURER OF MEDICAL EQUIPMENT AND DEVICES FOR NEONATES

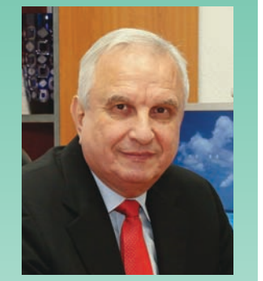
BLF-2001 TYPE INFANT INCUBATOR

HUNGARY

80 years experience in the field of medical device manufacturing



Parliament, Budapest



Dr Steiner Arnold
CEO,
President

Steiner András Arnold
Deputy CEO,
Vice President

Dear Partners,

Medical device manufacturing is one of the oldest and at the same time most innovative branches of Hungarian industry. Being among the oldest participants, MEDICOR gathered great experience in the field of neonatal care over the past decades. Thank to our partners in four continents, nowadays we are present in more than 90 countries. Due to its continuous development, MEDICOR BABYLIFE product line offers the latest cutting-edge technology in the field of neonatal care. Our results reflect our participation in countless successful national and international public tenders and business orders. We are especially proud of the fact that UNICEF has found our products worthy of a long-term supply agreement. The catalogue you are holding in your hands will introduce our company and the BLF-2001 type infant incubator to you. Thank you for your attention.

Table of Contents

Building on the past

In Hungary the dawn of medical device manufacturing dates back to the early 20th century.

The mid-20th century

- Development and manufacturing were carried out by small and medium-size enterprises – or SMEs, in today's terminology – in other fields of medical technology continued until the Soviet occupation of 1945, or rather the beginning of the Communist dictatorship in 1948-49, when small companies were nationalised and consolidated. In 1933, Magyar Siemens-Reiniger Művek Rt. became the only company on the Hungarian market; from 1963 on, operating under the name Medicor Művek.

- In the 1960s, semi-conductor technology and microprocessors made it possible to manufacture larger and more complex systems. The companies Elektronikus Mérőkészülékek Gyára (EMG) and Gamma Művek (Gamma) were pioneers in this field: EMG specialised in ECG and EEG technology, while Gamma developed a range of nuclear medical systems. Another company, the Medical Aids Factory played a major role in aiding rehabilitation by mass producing a variety of equipment to assist patients suffering from different types of disabilities.

The late 20th century

- Since the fall of Communism, the market for medical technology has undergone significant changes. New ownership and manufacturing structures have evolved and stabilised as large domestic companies were privatised and split up.

- In the period following the transition to democracy some 100 small and medium-size companies were established. Many of those continue to cherish and promote the strong traditions of the field, the majority remaining in Hungarian ownership even to date.

Széchenyi Chain Bridge, Budapest

MEDICOR: Then and now

MEDICOR Művek was formed from Hungary's medical technology companies in 1963. The company, whose operation involved development, manufacturing and trading, played a dominant role in the domestic industry for some 30 years.

MEDICOR Művek continued to expand and develop into the 1980s. At its peak, the company employed more than 10,000 people in its factories, research and development institute, as well as domestic and export trading branches. In this period, MEDICOR accounted for more than half of Hungary's medical technology manufacturing and had representation in 35 countries around the world. Some 85 to 90 percent of the production was made for export predominantly to COMECON countries.

Today, the manufacturing and service companies operating within MEDICOR Group are almost entirely Hungarian-owned and serve as the centre for the production of medical instruments and related services in Hungary.

MEDICOR ELEKTRONIKA has an equity of EUR 1,000,000 as a 100-percent Hungarian-owned company. The stock company plays a key role in the design and production of neonatal medical equipment relying on a global distribution network covering more than 90 countries all over the world. Its home treatment products also generate considerable revenue, particularly in Hungary.

MEDICOR ELEKTRONIKA's leading products include hospital equipment as well as home diagnosis and therapy products.

Hungarian Quality Product Award

BABYLIFE® BLF-2001
Neonatal incubator family

BABYLIFE® BLR-2100
Neonatal warming and resuscitation tables

MEDICOR

prompt service

reliable operation

easy to use

reliable spare parts supply

built-in protection functions

MEDICOR ELEKTRONIKA ZRT.

BABYLIFE® BLF-2001

Neonatal incubator family

- Exceptional safety
- Easy access to the baby
- Air curtain, double wall hood
- Automatic humidification
- Skin/Air controlled operation
- Silent operation
- Adjustable oxygen supply
- Micro-computer controlling
- Graphical LCD display indicating trend
- Numerous options

CE 2409

www.medicor.hu

MEDICOR

ISO 9001 ISO 13485

BABYLIFE® BLF-2001

Neonatal incubator family

BLF-2001 incubators have a remarkably wide range of configurations. The incubators can be ordered with the selected combination of the available options.

Exceptional safety

The functions and operation of BLF-2001 incubators meet the requirements of IEC-601-2-19 product standard those of the 93/42/EEC Directive. The materials used comply with to the hygienic and toxicological requirements and are monitored continuously. The development, production and quality assurance of the incubators are performed in accordance with the ISO 13485 and ISO 9001 standards.

Easy access to the baby

The hood has six fully transparent windows (with iris opening upon request) and a large (upon request two) door(s). An X-ray cassette can be inserted under the cradle or on a cassette holder tray (optional). The cradle with the baby can be placed into an inclined position (even electrically upon request; optional), and the baby can be removed from the incubator safely and quickly together with the cradle.

Air curtain, double wall hood

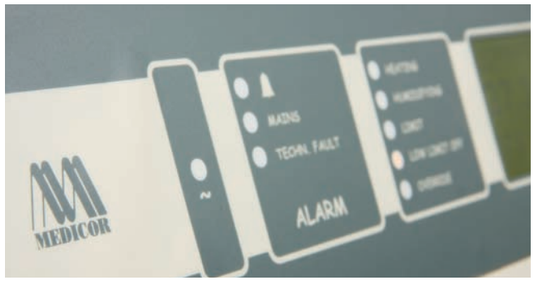
In the hood the air streams along the longitudinal axis of the baby's body. When the door is opened, an air curtain develops in the door. The hood of the unit may be single or double walled (optional).

Easy operation

The incubators are equipped with foil-covered keyboards and graphic LCD displays. Settings are easy to understand having the lowest possible number of controls. Set and real-time measured values are constantly shown on the LCD display.

Silent operation

The noise level in the hood is below 45 dBA. The opening and closing of windows is absolutely noiseless. The air flow rate is well below the value allowed by the relevant standards.



Variable oxygen supply

Oxygen supply in the hood is controlled by a rotameter between 21-40% (optional). An electronic oxygen servo unit provides higher oxygen concentration for more intensity between 21-75% (optional). The incubators may be ordered also with head hood and with warmed humidified oxygen servo control (21–75 (90)%) (optional).

Comfort

In the incubator, the baby's weight is measured with high accuracy by an electronic scale located under the cradle, the measured value is shown on the graphic display, while data are stored (optional). The height of the lying surface can be made electronically adjustable upon request (optional).

Micro-computer control

BLF-2001 incubators are micro-computer controlled. When switched on, a hardware and software self-test is launched. Possible errors are indicated on the graphic display. The trends and values measured every 3 or 24 or 170 hours can be retrieved from the memory of the incubator. The incubator may be connected to an external computer (by means of a software programme to be purchased separately), enabling monitoring and remote control, as well as the saving and printing of measured values and trends (optional).

The display of the BLF-2001 incubator is easy to read even from distance, indicating the following data, depending on the configuration:

- temperature of air in the hood
- humidity of air in the hood
- baby's skin temperature (optional)
- oxygen concentration (optional)
- weight (optional)
- second body temperature (optional)

The temperature control ranges of the incubator are as follows:

- in normal mode of operation in the case of 'air control' 27–37°C
- in the case of skin control 34–36°C.
- In 'override' operation in the case of 'air control' 37–39°C, in the case of 'skin control' 36–38°C.

Limits may be changed through a software programme upon the user's request during the production of the equipment, and settings (SET) are defined according to the requested increments. The humidity of the air in the hood is automatically controlled while the display is graded by 1% increments between 1–100. The increment of SET can be selected between 1–10%.

OPTIONS
BABYLIFE® BLF-2001

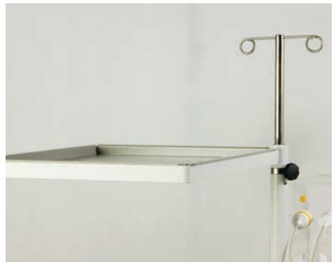
BB+BA (TB)
Additional built-in double or triple wall hood and access door

DBA
Front and back access door

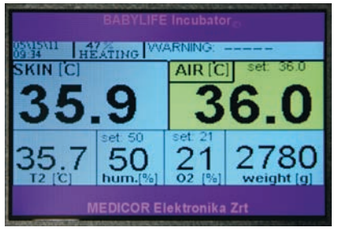
KB
Drawable cradle

FSZ
Additional built-in lower cabinets with drawers (instead of lower shelf)

MTP
Additional upper shelf with IV stand for monitor



SZK/ESZK
7" standard and 10.4" touchscreen colour



SC
High-accuracy built-in skin temperature control, display current/set value and trend

RTH(F)
Additional built-in measurement unit of second skin temperature (skin or rectal)

OF
Oxygen dosage to be regulated through flowmeter up to 40%, quick connector and cable, flow display

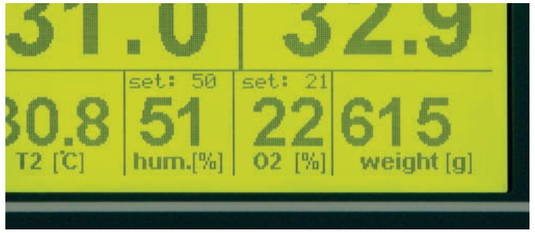
OM
Additional high-accuracy built-in oxygen concentration measurement unit up to 99%, digital display

SPO2
Built-in pulse oximeter

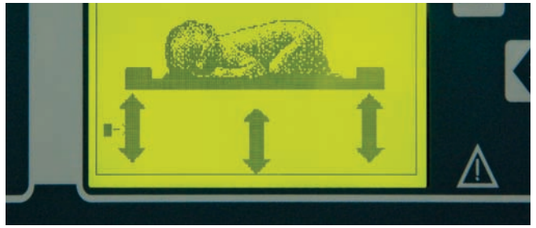
OSZ+OM
Additional built-in oxygen servo control unit within the hood between 21–75%, digital display with trend, quick connector

OSZ(F)
Complete oxygen servo control 21–75 (90)% in head-hood, oxygen head hood, display with trend (without oxygen cylinder)

EM
Additional high-accuracy built-in electrical scale, display of trend



EFE
Additional built-in trolley for free adjustment of incubator's height (900–1100 mm)



EB(F)
Additional built-in electrically freely variable cradle tilting

Standard Features and Options of BABYLIFE® BLF-2001 Neonatal Incubator*

HOOD / CANOPY	
Glass-like transparent single wall hood, x-ray compatible	**Standard**
Double or triple wall hood	Option
Front access door	**Standard**
Rear access door	Option
4 noiseless, easy to open hand port / window	**Standard**
Additional hand port instead of iris port	Option
2 iris port / window	**Standard**
6 tube port	**Standard**
Additional tube port (each)	Option

CRADLE (INFANT BED) / X-RAY CASSETTE TRAY	
Cradle with foam mattress, x-ray compatible	**Standard**
Anti-decubitus mattress	**Standard**
Gel mattress	Option
Net mattress	Option
Drawable cradle	Option
Mechanical cradle tilting (one step, up to 12°, both direction)	**Standard**
Electric cradle tilting (stepless, up to 15°, both direction)	Option
Space for x-ray casette under the cradle	**Standard**
Drawable x-ray casette tray	Option
Drawable x-ray casette tray with window	Option

STAND / IV POLE	
Heavy duty stand with 4 castors (2 lockable)	**Standard**
Electric height adjustment 900 - 1150 mm	Option
Electric height adjustment with foot pedal	Option
Instrument shelf on the stand	**Standard**
Cupboard with two drawers on the stand	Option
Gas cylinder holder	Option
Protector and instrument holder rails on each side	**Standard**
IV pole	Option
IV pole with monitor shelf	Option

DISPLAY / CAMERA / OPERATION / ALARM / NETWORK	
5" LCD display	**Standard**
7" colour LCD display	Option
10" colour touchscreen monitor	Option
Set / Display of date / time / humidity / temperature, etc.	**Standard**
Keypad lock	**Standard**
Display of heating intensity, 3/24/170 hours trend, real and measured values	**Standard**
Integrated camera	Option
Waterresistant, foil-covered keypad with lock	**Standard**
State-of-the-art microprocessor controller	**Standard**
UPS (Uninterruptible Power Supply) from 30 min operation time	Option
HEPA 13 air filter	**Standard**
Visual and audible alarms and backup sensors	**Standard**
Test button / Self test / Silence / Reset button	**Standard**
RS-232 connector	**Standard**
LAN connection	Option
WIFI connection	Option

HUMIDITY REGULATION	
Humidity servo (0-95%)	**Standard**
3 litres destillated and residual water reservoirs	**Standard**

TEMPERATURE REGULATION	
Air temperature servo control (25-39 °C)	**Standard**
Skin temperature servo control (34-38 °C)	Option
Peripherial skin temperature sensor	Option
Peripherial rectal temperature sensor	Option
Reusable / Disposable skin temperature sensor	Option
Reusable / Disposable rectal temperature sensor	Option

OXYGEN REGULATION / SCALE / SPO_2	
Oxygen dosage through flowmeter (21-40%)	Option
Oxygen concentration meter (0-100%)	Option
Oxygen servo in hood (21-75%)	Option
Oxygen servo in head-hood (21-95%)	Option
Oxygen servo in hood and head-hood (21-75/95%)	Option
Flowmeter with heated humidifier	Option
Oxygen sensor	Option
Built-in weighing scale with drawable cradle (0-10 kg)	Option
Built-in pulseoximeter with colour LCD	Option
Reusable / Disposable SpO_2 sensor	Option
SpO_2 extension cord	Option

ACCESSORIES	
Fixing head frame	Option
Head-hood	Option
Neonate protecting eyemask (disposable, 10 pcs)	Option
Reusable cover for hood	Option
Reusable cover for incubator	Option

LANGUAGE (SOFTWARE / USER MANUAL / SERVICE MANUAL)	
Language English	**Standard**
Language CN/DE/ES/FR/HU/RU	Upon request

**Additional features in case of demand. The models illustrated in this brochure show the specifications of neonatal incubators produced by MEDICOR for the European market. In part, they include optional equipment and accessories not fitted as standard. According to the specific requirements of other markets, alterations in models, standard and optional equipment, as described in this brochure, may occur. For more precise information about country-specific product versions, please contact your local partner. Subject to change in design and equipment.*

Technical data of BABYLIFE® BLF-2001 Neonatal incubator (basic version)*

PHYSICAL ATTRIBUTES (STANDARD VERSION)

Height / Packing	132/152 cm (52/60 in)
Width / Packing	85/95 cm (33/37 in)
Depth / Packing	60/70 cm (24/28 in)
Weight / Packing	70 kg (154 lbs)
Mains voltage	220/230V ±10% (default), 110/120V ±10% (upon request)
Nominal frequency	50/60Hz
Nominal power consumption	420VA
Operating ambient temperature range	+20°C - +30°C (68°F - 86°F)
Storage/transport ambient temperature range	-40°C - 70°C (-40°F - 158°F)
Operating (Storage) ambient RH range	30% - 90% (10% - 100%)
Operating (Storage) air pressure range	700 hPa - 1060 hPa (500 hPa - 1060 hPa)

HOOD SPECIFICATIONS

Access door opening height	30 cm (12 in)
Mattress tray size	34 x 68 cm (13 x 26 in)
Mattress to hood height	36 cm (14 in) default, up to 45 cm (18 in) as option
Mattress size	33 x 65 cm (13 x 27 in)

TEMPERATURE CONTROL MODES

Temperature control modes	Air (standard) / Skin (option)
Air mode control temperature range	20.0°C (68.0°F) to 37.0°C (98.6°F), in 0.1°C increments
Air mode control override temperature range	37.0°C (98.6°F) to 39.0°C (102.2°F), in 0.1°C increments
Skin mode control temperature range	34.0°C (93.2°F) to 36.0°C (96.8°F), in 0.1°C increments
Skin mode control override temperature range	36.0°C (96.8°F) to 38.0°C (100.4°F), in 0.1°C increments
Peripherial skin / Rectal temperature monitoring	Yes

PERFORMANCE

Air flow velocity across mattress	< 10 cm/sec
Temperature rise time at 22 °C (72°F) ambient	< 20 min
Temperature variability	< 0.5°C (0.9°F)
Temperature uniformity with a level mattress	< 0.8°C (1.4°F)
Correlation of the indicated air temperature to the actual incubator temperature	≤ 0.8°C (1.4°F)
Operating noise level in hood	< 45 dBA
Carbon Dioxide (CO_2) level (per EN60601-2-19)	< 0,2%
Micro air intake filter	HEPA13 - 99,95%
Particle size removal	0.3 micron

HUMIDITY SERVO CONTROL

Humidity control range	30% to 95% in 1% increments
Humidity control operating time without refilling	55 hours max. at 85% RH and 36°C (97°F) in Air Mode
Humidity control reservoir capacity	3000 ml
Humidity display accuracy	± 10% RH (between 10% and 90% at 20°C (68°F) to 40°C (104°F))

OXYGEN SERVO CONTROL

Oxygen control range	21% to 65%/75% (hood/head hood)
Oxygen control accuracy of full scale	± 3%
Oxygen display accuracy (100% calibration)	± 3%
Oxygen display accuracy (21% calibration)	± 3%
Oxygen display resolution	1%

WEIGHING SCALE

Weight range	0 to 10 kg (22 lbs)
Weight display resolution	1 gr or 1 oz
Weight accuracy	up to 5 kg ± 2 gr, over 5 kg ± 5 gr

DEVICE CLASSIFICATION

Protection class	Class I, Type BF, continuous operation
Ingress of liquids	IP20

TREND PARAMETERS

3/24/170-hour trend	– Air temperature
	– Skin temperature
	– Peripherial temperature
	– Relative humidity
	– Oxygen concentration
	– SpO_2 (Pulse Oximeter)
	– Heater power
	– Weight

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MEDICOR

Certificates


certiso

QUALITY MANAGEMENT SYSTEM CERTIFICATE

144485-14-03-31

Name of certified organisation:

MEDICOR Elektronika Zrt.

Headquarters:

1097 Budapest, Illatos út 9., HUNGARY

Scope:

Design, manufacture, distribution and service of electronic medical equipment

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 9001:2009
(ISO 9001:2008)

Issue: 1
Issued: 31 March 2014
First issued: 31 March 2014
Certified since: 28 March 1999

Expires:
30 March 2017


certiso

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 premature 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

Issue: 1
Issued: 15 May 2014
First issued: 15 May 2014
Start date of certified status: 28 March 1999

Expires:
14 May 2019

Valter PAPP, Dr.
General Manager


certiso

QUALITY MANAGEMENT SYSTEM CERTIFICATE

144486-14-03-31

Name of certified organisation:

MEDICOR Elektronika Zrt.

Headquarters:

1097 Budapest, Illatos út 9., HUNGARY

Scope:

Design, manufacture, distribution and service of electronic medical equipment

CE Certiso Ltd., Organisation for Certification and Testing on the Field of Medical and Hospital Engineering certifies that the quality management system applied by the organisation above meets the requirements of the following standard on the listed scope:

MSZ EN ISO 13485:2012
(ISO 13485:2003)

Issue: 1
Issued: 31 March 2014
First issued: 31 March 2014
Certified since: 28 March 1999

Expires:
30 March 2017


certiso

№ 144492-14-05-15
EC CERTIFICATE

Full Quality Assurance System
Directive 93/42/EEC on Medical devices, Annex II excluding (4)

ООО «ЦЕ ЦЕРТИЗО» (CE Certiso Kft.) контроль качества и сертификация медицинских изделий в больничной технике (NB 2409) свидетельствует о том, что система менеджмента качества нижеследующего предприятия по указанные категории медицинских изделий отвечает соответствующим требованиям директивы.

Название предприятия:

ЗАО «МЕДИКОР Электроника»

Юридический адрес:

Венгрия, 1097 г. Будапешт, ул. Иллатош д. 9.

Область сертификации:

Электронные медицинские изделия

Действительность сертификата распространяется на следующее оборудование:

Номенклатура	Тип	Применение	Модель	Класс риска
Группа закрытого клинического инкубатора для новорождённых	BABYLIFE®	Выхаживание новорождённых и недоношенных младенцев интенсивная терапия	BLF-2001 BLF-2001B	II.b
Группа открытого обогревательного и реанимационного рабочего места	BABYLIFE®	Выхаживание новорождённых требующих немедленного ухода	BLR-2100 BLR-2100A	II.b
Группа ламп синего цвета	BABYLIFE®	Предотвращение и лечение желтухи (гипербилирубинемия)	KLA-145 KLA-145M	IIa
Группа тонометров	MEDICOR®	Измерение артериального давления и пульса	SE-2000 SE-4000 SE-7000	IIa
Группа приборов T.E.N.S.	MEDICOR®	Стимулирование мышц и мышц, болеутоляющий прибор	SE-30 SE-33 SE-35	IIa

Настоящий сертификат действителен при условии ежегодных успешных надзорных аудитов.
Номер соответствующего аудитного доклада 78-CE-140303

Номер выдачи сертификата: 1
Дата выдачи сертификата: 15 мая 2014
Дата первой выдачи сертификата: 15 мая 2014
Дата начала срока действия сертификата: 28 марта 1999

Дата истечения срока действия сертификата:
14 мая 2019

Валтер Папп
генеральный менеджер

MEDICOR

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Fax: +36 (1) 280-6336

www.medicor.hu

Contact:
E-mail: sales@medicor.hu

ISO 9001 ISO 13485