EC Certificate

mdc medical device certification GmbH
Notified Body 0483
herewith certifies that

Gerium Medical Ltd.
6, Ha-Kishon Street
Yavne, 8122017
Israel

for the scope

BiliCare
(non-invasive transcutaneous bilirubinometer)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with the conformity of the products with metrological requirements.

The mdc audit has proven that this quality system meets all requirements according to

Annex II – excluding Section 4 of the Council Directive 93/42/EEC

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2018-04-04
Valid until	2023-04-03
Registration no.	D1355800008
Report no.	P18-00164-113696
Stuttgart	2018-04-03

Head of Certification Body

medical device certification mdc

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-246.10.06

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

For electronic publication only

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-BS-244.10.08

2022 -02- 25

Product Service

EC Certificate

EC Type-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 011882 0078 Rev. 00

Manufacturer: **PHYSIO-CONTROL, Inc.**
11811 Willows Road N.E.
Redmond WA 98052
USA

Product: **Defibrillators**
Cardiac Defibrillator Accessory

The Certification Body of TÜV SÜD Product Service GmbH declares that a type examination has been carried out on the respective device type in accordance with MDD Annex III (4). This representative sample for the envisaged production conforms to the requirements of this Directive. For marketing of class III devices an additional Annex IV or V certificate is mandatory. For marketing of class IIb devices an additional Annex IV, V or VI certificate is mandatory. See also notes overleaf.

Report no.: 72157767

Valid from: 2020-03-17
Valid until: 2024-01-27

Date, 2020-03-17

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

KOI IJA T...
Direktorin
Algis Bakutis
2022 -02- 25

TÜV SÜD Product Service

EC Certificate

EC Type-Examination Certificate
Directive 93/42/EEC on Medical Devices (MDD), Annex III
(Devices in class IIb or III)

No. G5 011882 0078 Rev. 00

Model(s): **Cardiac Defibrillator Accessory Defibrillator Internal Handles and Paddles for LIFEPAK 12, LIFEPAK 15, LIFEPAK 20, and LIFEPAK 20e**

Parameters: Paddle diameters 2.5 cm, 3.8 cm, 5.1 cm, 6.4 cm, 8.9 cm

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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TÜV®

Patient Warming Business
3M Infection Prevention Division
3M Health Care

Arizant Healthcare Inc., a 3M company
10393 W 70th Street
Eden Prairie. MN 55344
800 733 7775

3M

CE 0470

EC DECLARATION OF CONFORMITY

We, **Arizant Healthcare Inc., a 3M company (Manufacturer)**
10393 West 70th Street
Eden Prairie, Minnesota, 55344 USA

declare under sole responsibility that the **Bair Hugger® Model 750 Warming Unit** to which this declaration relates meets the essential health and safety requirements and is in conformance with the relevant EC directives listed below using the relevant section of the following EC standards and other normative documents. For the CE Mark to remain valid, this product must be used exclusively with Arizant Healthcare Inc. Bair Hugger Warming/Cooling Blankets or Bair Paws Warming/Cooling Gowns.

EU Medical Device Directive – Council Directive 93/42/EEC of June 14, 1993 as amended by Directive 2007/47/EC Concerning Medical Devices
(Including standards required to prove compliance to the Essential Requirements)

The device named in this Declaration is classified as IIb as it is an integral part of a Class IIb system. The classification is based on the requirements of Rule 9 of Annex IX of the Medical Device Directive (MDD).

The **Bair Hugger Model 750 Warming Unit**, including all revisions, complies with all of the applicable requirements of the Essential Requirements of the MDD, when used as directed.

The manufacturer's Quality Management System meets the requirements of ISO 13485:2003 as indicated on **NEMKO** certificate number 908077.
The manufacturer's **EC Certificate number is EU1112417.**
The EC registration has been granted by **NEMKO**, Oslo, Norway.
The CE Mark is applied under the guidelines of Annex II of the MDD.
The CE marking has been affixed on the device according to Article 17 of the MDD.

Date of initial CE Marking on this product: 1/03

Arizant Healthcare Inc., a 3M company's EU Authorized Representation (as defined in Article 14 of the Medical Device Directive: 93/42/EEC): 3M Deutschland GmbH, Health Care Business
Carl-Schurz-Str. 1, 41453 Neuss, Germany

David Westlin
Director of Regulatory Affairs

Rev L, 01/2012

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

KONTRARA
Direktorius
Algis Bakutis

2022 -02- 25

Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 01 70231 011

Manufacturer:

Spacelabs Healthcare Ltd.
Unit B, Foxholes Centre
John Tate Road
Hertford
Hertfordshire SG13 7DT
UNITED KINGDOM

Product Category(ies):

ECG Recorders, ECG Analysers, Ambulatory NIBP recorders, Cardiac Information Management Systems, ECG Receiving System, ECG Stress Test Systems, Anaesthetic Machines, Anaesthetic Vaporisers and Circle Absorbers

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 75937670

Valid from: 2017-02-12
Valid until: 2023-02-11

Date, 2017-02-03

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

A1 / 04.11

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KT IMA TIKRA
Direktorius
Algis Bakutis
2022 -07- 29

Product Service

EC Certificate
Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 17 01 70231 011

Facility(ies):

Spacelabs Healthcare Ltd.
Unit B, Foxholes Centre, John Tate Road, Hertford, Hertfordshire
SG13 7DT, UNITED KINGDOM

Spacelabs Healthcare Ltd.
43 Moray Place, Edinburgh, Lothian EH3 6BT, UNITED
KINGDOM

Spacelabs Healthcare, Inc.
2802 Coho Street, Suite 202, Madison WI 53713, USA

TÜV SÜD Product Service GmbH · Zertifizierstelle · Ridlerstraße 65 · 80339 München · Germany

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