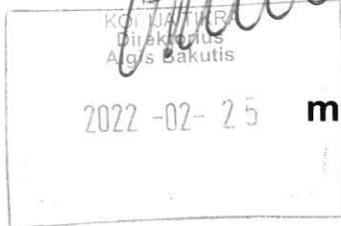


EC Certificate



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



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

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Product Service

2022-02-25

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

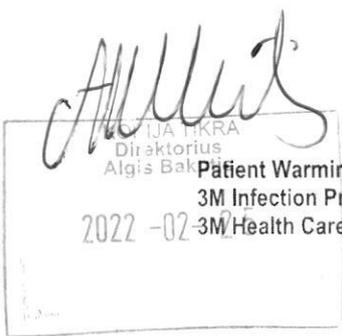
Valid until: 2024-01-27

Date, 2020-03-17

Handwritten signature of Christoph Dicks

Christoph Dicks
 Head of Certification/Notified Body

TÜV SÜD
 ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT



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



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

Director of Regulatory Affairs

Rev L, 01/2012

10393 West 70th Street, Eden Prairie, MN 55344 USA
(952) 947-1200 (800) 800-4346 Fax (952) 947-1400
www.arizant.com

[Handwritten Signature]
KOTISA TIKRA
Direktoriu
Algis Bakutis



Product Service

2022-07-29
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):

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