



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



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 099651 0003 Rev. 00

Manufacturer:

TriMedika Ltd

Unit 3 E3 Building, Springvale Campus
398 Springfield Road
Co Antrim
Belfast, Northern Ireland, BT12 7DU
UNITED KINGDOM

Product Category(ies): **Infra Red Thermometers for Clinical use**

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.: 75947171

Valid from: 2020-03-27

Valid until: 2024-05-26

Date, 2020-03-27

Christoph Dicks
Head of Certification/Notified Body



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 099651 0006 Rev. 00

Manufacturer:

TriMedika Ltd

Whiterock Business Park
739 Springfield Road
Belfast, BT12 7FP
UNITED KINGDOM - NORTHERN IRELAND

This Confirmation Statement
is only valid in combination
with the following
EC Certificate (MDD):

G1 099651 0003 Rev. 00

This Confirmation Statement confirms the validity of the aforementioned EC Certificate (MDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer
data initiated 26 May 2021 or later.

The conditions laid down in Article 120 (3) of Regulation (EU) 2017/745 on medical devices for
placing devices on the market and putting into service apply. For details and confirmation statement
validity see: [www.tuvsud.com/ps-cert?q=cert:GCQ_099651_0006 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:GCQ_099651_0006_Rev._00)

Report No.:

75959608_CN

Valid until:

2024-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue Date: 2024-03-05

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 099651 0006 Rev. 00**Product Category(ies): Infra Red Thermometers for Clinical use****Description of
Change:**

Change of address from :

Trimedika Ltd, Unit 3 E3 Building, Springvale Campus, 398 Springfield Road, Co Antrim, Belfast, Northern Ireland, BT12 7DU, United Kingdom

TO:

Trimedika Ltd,Whiterock Business Park, 739 Springfield Road, Belfast, BT12 7FP, United Kingdom