



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 034633 0010 Rev. 00

Manufacturer:

ewimed Switzerland AG

Freiburgstrasse 453

3018 Bern

SWITZERLAND

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

G1 034633 0008 Rev. 01

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 034633 0010 Rev. 00

Report No.:

713318747

Valid until:

2024-05-26

Christoph Dicks

Head of Certification/Notified Body

Issue Date: 2024-02-23

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No. GCQ 034633 0010 Rev. 00**Product Category(ies): Infant radiant warmer****Description of
Change:****1. Change of Company Name****From: Nufer Medical AG****To: ewimed Switzerland AG****2. Change of Address and Relocation of Headquarter****From: Morgenstrasse 148, 3018 Bern, SWITZERLAND****To: Freiburgstrasse 453, 3018 Bern, SWITZERLAND**