



Product Service

Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 021697 0023 Rev. 00**Manufacturer:****Honeywell Healthcare Solutions GmbH**

Alter Holzhafen 18

23966 Wismar

GERMANY

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

G1 021697 0017 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.

Report No.:

713227588

Valid until:

2024-05-26

Christoph Dicks

Head of Certification/Notified Body

Issue Date: 2022-05-18



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Confirmation Statement on validity of EC Certificate (MDD)

pursuant to Directive 93/42/EEC concerning medical devices

No. GCQ 021697 0023 Rev. 00

**Product Category(ies): Oxygen Saturation Sensors and Monitors,
Sensors and Control Units for Monitoring of
Respiratory Parameters and Gas Exchange,
Non-invasive Blood Pressure Equipment,
Temperature Sensor**

**Description of
Change:**

Change of company name from:

EnviteC - Wismar GmbH

to

Honeywell Healthcare Solutions GmbH