



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** **G1 021697 0017 Rev. 01**  
**is only valid in combination**  
**with the following**  
**EC Certificate (MDD):**

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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**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**