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Zentralstelle der Länder  
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bei Arzneimitteln und  
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Product Service

# EC Certificate

Product Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex VI  
(Devices in Class I with measuring function)

**No. G3M 036993 0007 Rev. 01**

**Manufacturer:** **TRACOE medical GmbH**  
Reichelsheimer Str. 1/3  
55268 Nieder-Olm  
GERMANY

**Facility(ies):** TRACOE medical GmbH  
Reichelsheimer Str. 1/3, 55268 Nieder-Olm, GERMANY

**Product Category(ies):** **cuff pressure monitor (cpm)**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for final inspection and testing of the respective devices / device categories in accordance with MDD Annex VI. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report no.:** 713167692

**Valid from:** 2020-03-25

**Valid until:** 2024-05-26

**Date,** 2020-03-25

Christoph Dicks  
Head of Certification/Notified Body

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AA / 07.17