

# Declaration of Conformity

MANUFACTURER  
RADIOMETER BASEL AG  
Austrasse 25  
CH-4051 Basel  
Switzerland

Product Name	Ref.No.	GMDN	CE-Mark
TCM5	393-500	46934	2015.12.08

Serial Number: from 393-500R1001N001

We hereby declare that the product(s) described above meets the applicable requirements of Directive 93/42/EEC of the European Council of June 14 1993 concerning medical devices (MDD) as specified in Annex I and II.

The conformity assessment procedure was performed according to Annex II, 3

Class: IIb.

The product meets the requirements of the following safety and performance standards:

IEC 60601-1:2005 +A1:2012; IEC 60601-1-2:2007; IEC 60601-1-6:2010 + A1:2013;  
IEC 60601-1-8:2006 + Am. 1:2012; IEC 60601-1-11:2015; IEC 60601-2-23:2011;  
ISO 80601-2-61:2011; IEC 62366:2007 + A1:2014; IEC 62304:2006+AMD1:2015; EN  
1789:2007+A2:2014;

The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II, Section 3 of the Medical Device Directive.

#### Name/Address of Notified Body

TÜV SÜD Product Service GmbH (ID# 0123)  
Ridlerstrasse 65  
80339 München  
Germany

Authorized Signature:



Name: Christoph Feulner

Date: 2018.03.08

Manager RA & QA

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