

Declaration of Conformity

EC/MDD Declaration of Conformity

This is a declaration made in accordance with the requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).

Manufacturer: Medset Medizintechnik GmbH
Curslacker Neuer Deich 66
21029 Hamburg, Germany

Product: **ABPM System**
PADSY-RR (SCANLIGHT III)

<u>Consisting of:</u>	<u>Article No.</u>
ABPM Recorder SCANLIGHT III, version B	AAG120002
Software PADSY-RR (SCANLIGHT III) , Version 1.11	AAG127101

Classification: IIa

<u>Product Name:</u>	<u>Article No.</u>
Connector for Blood Pressure Cuff, SCANLIGHT II and III	AAZ120001
Recorder bag SCANLIGHT II and III	AAZ120002
PC-Interface L, Serial, SCANLIGHT II and III	AAZ121004
PC-Interface U, Serial/USB, SCANLIGHT II and III	AAZ121007
Battery charging set, SCANLIGHT II and III	AAZ122001
Blood Pressure Cuff XS, Complete, SCANLIGHT II and III	AAZ124105
Blood Pressure Cuff S, Complete, SCANLIGHT II and III	AAZ124101
Blood Pressure Cuff M, Complete, SCANLIGHT II and III	AAZ124102
Blood Pressure Cuff L, Complete, SCANLIGHT II and III	AAZ124103
Blood Pressure Cuff XL, Complete, SCANLIGHT II and III	AAZ124104
USB Adapter, 4x RS232/ USB for Apple	BBZ5052
USB/ serial Adapter, 1x RS-232/ USB Interface	BBZ5050

Classification: I

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We declare on our own authority that each listed kind of medical device to which the Full Quality Assurance Procedures (Annex II) have been applied complies with the applicable provisions of the essential requirements of the European Directive 93/42/EEC.

Notified Body: Dekra Certification GmbH
Handwerkstraße 15, 70565 Stuttgart, Germany

CE 0124

**Harmonised
standard Applied:**

EN 1041:2008
EN 1060-1:1995+A2:2009
EN 1060-3:1997+A2:2009
EN 1060-4:2004
EN ISO 10993-1:2009
EN ISO 14971:2009
EN ISO 15223-1:2012
EN 60601-1:1990/A1:1993/A2:1995/A13:1995
EN 60601-1-1:2001
EN 60601-1-2:2007
EN 60601-1-4:1996/A1:1999
EN 60601-1-6:2007
EN 62304:2006/AC:2008
EN 62366:2008

Place and Validity date from:

Hamburg, 13th June 2013

Name and signature of authorized person:



Klaus Kophstahl
- Head of Quality Management -