HANS DINSLAGE GmbH File EC Declaration of Conformity

SBM 36_EC DoC_Hans Dinslage_20200925

Manufacturer:

Hans Dinslage GmbH (see address in footer)

Product category:

Blood pressure monitor

Product type:

SBM 36/1 (Model: SBM 36)

The product specified above is in conformity with the provisions of the following Union legislation and harmonized standards.

93/42/EEC

Medical device directive (MDD)

UMDNS code and name:

16-174 Blood Pressure Monitor, electronic, manual

Classification/applied rule(s):

Class Ila/rule 10

Conformity assessment

Annex VII in conjuction with annex V

procedure:

The notified body mdc medical device certification GmbH, located at Kriegerstr. 6, 70191 Stuttgart, Germany, identification number 0483, issued in the course of the mentioned conformity assessment procedure the following certificate:

Certificate no. and validity:

D1326900032, valid to 2024-05-26

IEC 60601-1:2012 EN 60601-1-2:2015

IEC 80601-2-30:2009 + A1:2013

EN ISO 81060-1:2012 EN 1060-3:1997 + A2:2009

EN 1060-4:2004

2011/65/EU

Restrictions of the use of certain hazardous substances in electrical and electronic

equipment (ROHS)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of:

Hans Dinslage GmbH

Place, date of issue:

Ulm, 25.09.2020

Name, function, signature,

anne, idriction, signature,

Werner Meternek, Director R&D / RA

stamp:

Hans Dinslage GmbH