HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SBM 67_EC DoC_Hans Dinslage_20210421

Manufacturer: Hans Dinslage GmbH (see address in footer)

Blood pressure monitor Product category:

Product type: **SBM 67**

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

procedure:

2011/65/EU

Annex II - excluding section 4

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: D1326900034, valid to 2024-05-26

EN 60601-1:2005 + A1:2012

EN 60601-1-2:2015 ISO 81060-1:2007

IEC 80601-2-30:2009 + A1:2013 EN 1060-3:1997 + A2:2009 EN ISO 81060-2:2014

2014/53/EU Radio equipment directive (RED)

EN 62479:2010

EN 301 489-1 V1.9.2 (2011-09) EN 301 489-17 V2.2.1(2012-09) EN 300 328 V2.1.1 (2016-11)

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, 21.04.2021

Name, function, signature, Daniel Kämmerer, Team Leader RA

stamp: Hans Dinslage GmbH Riedlinger Str. 28 88524 Uttenweiter