

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SBM 37_EC DoC_Hans Dinslage_20210525

Manufacturer: Hans Dinslage GmbH (see address in footer)

Product category: Blood pressure monitor

Product type: SBM 37

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 IIa/rule 10

Conformity assessment procedure: 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

IEC 60601-1:2012
EN 60601-1-2:2015
IEC 80601-2-30:2009 + A1:2013

2014/53/EU Radio equipment directive (RED)

EN 62479:2010
EN 50663:2017
EN 301 489-1 V2.2.3 (2019-11)
Draft EN 301 489-17 V3.2.2 (2019-12)
EN 300 328 V2.2.2 (2019-07)

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, 25.05.2021

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

Hans Dinslage GmbH
Riedlinger Str. 28 • 88524 Uttenweiler