

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SME 85_EC DoC_Hans Dinslage_20210421

Manufacturer: Hans Dinslage GmbH (see address in footer)

Product category: Electrocardiograph

Product type: SME 85

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: 12-599 ECG-Monitor

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

EN 60601-1:2006 + A1:2013
 EN 60601-1-2:2015
 IEC 60601-2-25:2011
 IEC 60601-2-47:2001

2014/53/EU Radio equipment directive (RED)

EN 62479:2010
 EN 301 489-1 V2.1.1 (2017-02)
 EN 301 489-17 V3.1.1 (2017-02)
 EN 55032:2015
 EN 61000-4-3:2006 + A1:2008 + A2:2010
 EN 61000-4-2:2009
 EN 300 328 V2.1.1 (2016-11)

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, 21.04.2021

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

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