

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SPO 55_EC DoC_Hans Dinslage_20210705

Manufacturer: Hans Dinslage GmbH (see address in footer)

SRN: DE-MF-000005488

Product category: Pulse oximeter

Product type: SPO 55

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

(EU) 2017/745 Medical device regulation (MDR)

Basic-UDI-DI: 4066299HMD0003JQ

CND code and name: Z1203020408 (Pulse oximeters)

Classification/applied rule(s): Class IIa/rule 10

Conformity assessment procedure: Annex IX

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: D1326900036

IEC 60601-1:2012
IEC 60601-1-2:2014
ISO 80601-2-61:2017

2014/53/EU Radio equipment directive (RED)

EN 62479:2010
EN 301 489-1 V2.2.0 (2017-03)
EN 301 489-17 V3.2.0 (2017-03)
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, 05.07.2021

Name, function, signature, stamp: Marco Bühler, Managing Director

