

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	Date	2024-02-01

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 following specifications.

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

Basic-UDI-DI: 4066299SPO552D

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

Conformity assessment procedure: Annex IX, Chapter I

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: D1326900045, valid to 2026-04-08

2014/53/EU Radio equipment directive (RED)

IEC 60601-1:2005 + A1:2012 + A2:2020
IEC 60601-1-2:2014 + A1:2020
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)

EN IEC 63000:2018

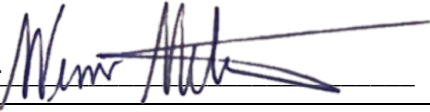
This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of: Hans Dinslage GmbH

Place, date of issue: Ulm, 2024-02-01

Name, function, signature, stamp: Werner Meternek, Director Quality Management & Regulatory Affairs

ppa.



Hans Dinslage GmbH
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