

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	Date	2025-02-03

Manufacturer:

Hans Dinslage GmbH (see address in footer)

SRN:

DE-MF-000005488

Product category:

Pulse oximeter

Product type:

SPO 55

Intended use:

The pulse oximeter is used for non-invasive measurement of arterial oxygen saturation (SpO₂) and heart rate (pulse rate) at home and in hospitals (not in AP and APG-class rooms). This device is not suitable for long-term measurement.

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

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, 2025-02-03

Name, function, signature, stamp:

Werner Meternek, Director Quality Management & Regulatory Affairs

ppa. 

Hans Dinslage GmbH

Riedlinger Str. 28 • 88524 Uttenweiler