

<b>HANS DINSLAGE GmbH</b>	<b>Title</b>	<b>EC Declaration of Conformity</b>
	<b>File</b>	SPO 55_EC DoC_Hans Dinslage_20230504.docm

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: D1326900042, valid to 2026-04-08

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)

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, 2023-05-04

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

i.V.  **Hans Dinslage GmbH**  
Riedlinger Str. 28 • 88524 Uttenweiler