

<b>HANS DINSLAGE GmbH</b>	<b>Title</b>	<b>EC Declaration of Conformity</b>
	<b>File</b>	SPO 55_EC DoC_Hans Dinslage_20220718

Manufacturer: Hans Dinslage GmbH (see address in footer)

Product category: Pulse oximeter

Product type: SPO 55

The product specified above is in conformity with the following specifications.

93/42/EEC Medical device directive (MDD)

UMDNS code and name: 17-148 Oximeter, Pulse

Classification/applied rule(s): Class IIb/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

IEC 60601-1:2012  
IEC 60601-1-2:2014  
IEC 60601-1-11:2015  
ISO 80601-2-61:2017

2014/53/EU Radio equipment directive (RED)

EN 62479:2010  
Draft EN 301 489-1 V2.2.0 (2017-03)  
Draft EN 301 489-17 V3.2.0 (2017-03)  
EN 300 328 V2.2.2 (2019-07)

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, 2022-07-18

Name, function, signature, stamp: Daniel Kämmerer, Team Lead Regulatory Affairs

**Hans Dinslage GmbH**  
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