


HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SPO 18_EC DoC_Hans Dinslage_20210421

Manufacturer:	Hans Dinslage GmbH (see address in footer)
Product category:	Pulse Oximeter
Product type:	SPO 25 (Model: SPO 18)
The product specified above is in conformity with the provisions of the following Union legislation and harmonized standards.	
93/42/EEC	Medical device directive (MDD)
UMDNS code and name:	17-148 Oximeter, Pulse
Classification/applied rule(s):	Class IIa/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
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, 21.04.2021
Name, function, signature, stamp:	Daniel Kämmerer, Team Leader RA  Hans Dinslage GmbH Riedlinger Str. 28 • 88524 Uttenweiler