

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	File	SEM 22_EC DoC_Hans Dinslage_20200324

Manufacturer: Hans Dinslage GmbH (see address in footer)

Product category: TENS device

Product type: SEM 24 (Model: SEM 22)

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: 13-782 Stimulator, Electroanalgesia, transcutaneous, electrical nerve stimulation

Classification/applied rule(s): Class IIa/rule 9

Conformity assessment procedure: Annex VII in conjunction with annex V

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: D1326900032, valid to 2024-05-26

EN 60601-1:2006 + A11:2011 + A1:2013
EN 60601-1-2:2015
IEC 60601-2-10:2012

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, 24.03.2020

Name, function, signature, stamp: Werner Meternek, Director R&D / RA

i.v.  **Hans Dinslage GmbH**
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