

HANS DINSLAGE GmbH	Title	EC Declaration of Conformity
	Date	2025-10-23

Manufacturer: Hans Dinslage GmbH (see address in footer)

SRN: DE-MF-000005488

Product category: TENS devices

Product type: SEM 46

Intended use: The device is intended to treat pain using TENS technology (transcutaneous electrical nerve stimulation). This pain relief can be applied to different areas of the human body

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

(EU) 2017/745 Medical device regulation (MDR)

Basic-UDI-DI: 4066299SEM46XJ

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

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: D1326900049, 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, 2025-10-23

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

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