

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: Bite healers

Product type: SBR 55 (Model: SBR 53)

Intended use: The insect bite healer is intended for relieving itching and swelling caused by insect bites or stings by applying heat (local hyperthermia).

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

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

Basic-UDI-DI: 4066299SBR55XP

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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