HANS DINSLAGE GmbH Title EC Declaration of Conformity

File SBR 55\_EC DoC\_Hans Dinslage\_20210324

Manufacturer:

Hans Dinslage GmbH (see address in footer)

Product category:

Bite healer

Product type:

**SBR 55** 

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:

15-610 Warming Units

Classification/applied rule(s):

Class Ila/rule 9

Conformity assessment

Annex II - excluding section 4

procedure:

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

EN 60601-1:2006 + A1:2013

EN 60601-1-2:2015

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, 24.03.2021

Name, function, signature,

stamp:

Werner Meternek, Director R&D / RA

Hans Dinslage GmbH