

EC - DECLARATION OF CONFORMITY



No.: EM49_CE_DoC, valid to 2019-07-02
Manufacturer: Beurer GmbH
Address: Söflinger Str. 218
89077 Ulm
Germany

Förderndes Mitglied der
Deutschen Hochdruckliga
Förderndes Mitglied der
Deutschen Diabetes Stiftung

This declaration of conformity is issued under our sole responsibility.

UMDNS code and name: 13-782 Stimulator, Electroanalgesia, transcutaneous
electrical nerve stimulation

Category code and category: 04 Electrical and mechanical medical devices

Classification Rule/ Class: Rule 9/ Class IIa

Product name: EM49

Expiry Date: 2019-07-02

The object of the declaration described above is in conformity with the relevant Community harmonisation
legislation:

Directives _Date of last revision: CD 93/42/EEC (MDD) amended with 2007/47/EEC_
2010-03-21
CD 2011/65/EC (ROHS)_2011-06-08

Conformity assessment procedure: Annex II – excluding Section 4 of CD 93/42/EEC (MDD)

Relevant harmonised standards: EN 60601-1: 2006 + A1: 2013
EN 60601-1-2: 2007
EN 60601-2-10: 2015

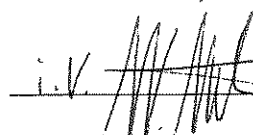
The notified body mdc - medical device certification GmbH, located at Kriegerstr. 6, D-70191 Stuttgart,
identification number 0483, issued in the course of conformity assessment procedure the following
certificate:

Certificate No._issued on: D1311700028_2017-11-29, valid to 2019-07-02

Signed for and on behalf of: Beurer GmbH

Place, date of issue: Ulm, 2017-12-18

Name, function and signature: Werner Meternek, Director R&D

 Beurer GmbH
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