

EC Declaration of Conformity Title

File FT 95_EC DoC_Beurer_20200527

Manufacturer: Beurer GmbH (see address in footer)

Product category: Infrared thermometer

FT 95 Product type:

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: 17-888 Thermometer, Infrared, Skin

Classification/applied rule(s): Class Ila/rule 10

Conformity assessment

procedure:

Annex II - excluding section 4

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:

D1311700043, valid to 2024-05-26 Certificate no. and validity:

EN 60601-1:2006 + A11:2011 + A1:2013 + A12:2014

EN 60601-1-2:2015 ISO 80601-2-56:2009 EN 12470-5:2003

2014/53/EU Radio equipment directive (RED)

> Draft EN 301 489-1 V2.2.0 (2017-03) Draft EN 301 489-17 V3.2.0 (2017-03)

EN 55032:2015 EN 61000-4-2:2009

EN 61000-4-3:2006 + A1:2008 + A2:2010

Restrictions of the use of certain hazardous substances in electrical and electronic 2011/65/EU

equipment (ROHS)

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Signed for and on behalf of: Beurer GmbH

Place, date of issue: Ulm, 27.05.2020

Name, function, signature,

stamp:

Daniel Kämmerer, Team Leader RA

Beurer GmbH Söflinger Straße 218 · 89077 Ulm

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