

UEBE Medical GmbH, Bgm.-Kuhn-Str. 22, 97900 Kulsheim

Kunden der
UEBE Medical GmbH

01.08.2022

Erklärung zur Baugleichheit

Sehr geehrte Damen und Herren,

beim, durch die Uebe Medical GmbH als Händler vertriebenen Produkt Non-Contact Thermometer Model „Domotherm Free“ (Art.Nr. 0885), handelt es sich um das baugleiche Produkt Model: „NT17“ des Herstellers AVITA Corporation.

Mit besten Grüßen

i.A. **Andreas Hußmann** (Dipl.-Ing. (FH))
Quality Management (QMB) / Ass. Regulatory Affairs



EC Declaration of Conformity

APS0-01-051

Manufacturer:

AViTA Corporation

**9F, No.78, Sec. 1, Kwang-Fu Road, San-Chung
District, New Taipei City 24158 Taiwan, R.O.C.**

whose single Authorized Representative:

MDSS GmbH

**Schiffgraben 41
30175 Hannover, Germany**

We, the manufacturer, herewith declare that the products

Product: Non-Contact Thermometer

Model: NT17

GMDN Code: 17888

(including system components and accessories)
meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX Rule 10, of the Directive 93/42/EEC. It bears the mark



The product concerned has been designed and manufactured under a quality management system according to Annex II, excluding sec.4, of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

SGS Fimko Ltd
Takomotie 8
FI-00380 Helsinki, Finland
Notified Body 0598
Country : Finland
Certificate No.: FI20/07003
Issue date: 2020.02.25
Expiry date: 2024.05.24

following the procedure relating to the EC Declaration of Conformity set out in Annex II (excluding sec.4) & Annex VII, of Directive 93/42/EEC

The above mentioned declaration of conformity is exclusively under the responsibility of

AViTA Corporation

New Taipei City,
2020 / 05 / 20


QA Director
Legally binding signature, Function