EC Declaration of Conformity

Doc. No.:【AIQP-003-181】

Manufacturer:

AViTA Corporation
9F, NO.78, Sec.1, Kwang-Fu Rd., San-Chung District, New Taipei City, Taiwan, R.O.C.

whose single Authorized Representative:

Wellkang Ltd.,
Suite B, 29 Harley Street, LONDON W1G 9QR, England, United Kingdom

We, the manufacturer, declare under our sole responsibility that the product to which this declaration relates is in conformity with the following standard(s) or other normative document(s) and proves the conformity of the designated product with the provisions of the EC Directive(s):

Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

Product Model: NT18, #105801, REF 901094
Product Name : CareTemp Touch Free Thermometer

(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 of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II, without the Annex II.4, of Directive 93/42/EEC, and the essential requirement of Annex I pertaining to medical devices

Standards Applied:

Reference Number	Title	Date of Issue
ISO 80601-2-56	Medical Electric Equipment – Part 2-56: Particular requirements for Basic Safety and Essential Performance of clinical thermometers for body temperature measurement	2009
EN IEC 60601-1	Medical Electric Equipment – Part 1: General requirements for Basic Safety and Essential Performance	2010
EN IEC 60601-1-2	Medical Electric Equipment – Part 1-2: General requirements For Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests	2010
EN ISO 14971	Medical devices – Application of risk management to medical devices.	2012
EN ISO 15223-1	Medical devices - Symbols to be used with medical devices labels, labelling and information to be supplied - Part 1: General requirements	2012

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EN1041	Information supplied by the manufacturer with Medical Device	2008
IEC 62304	Medical Device Software – Software Life Cycle Process	2006
EN 62366	Medical devices - Application of usability engineering to medical devices	2008
EN 60601-1-6:	Medical electrical equipment -- Part 1-6: General Requirements for basic safety and essential performance - Collateral Standard: Usability	2010
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2015
EN 50581	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances (RoHS)	2012
EN 50419	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	2006
FDA 21 CFR PART 820	Quality System Regulation QSR Requirements for Medical Device Manufacturers for FDA 21 CFR Part 820 Compliance	

The part specification 30047003 / Ver D

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

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Country : Germany
Certificate No.: HD 60099060 0001
Issue date: 2015.03.12
Expiry date: 2020.03.02

following the procedure relating to the EC Declaration of Conformity set out in Annex II, without the Annex II.4, of Directive 93/42/EEC

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

AViTA Corporation

AVITA CORPORATION

Authorized Signature

New Taipei County, Taiwan by March 24, 2015

Place, date

Legally binding signature, Function

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