

EC Certificate Full Quality Assurance System FI20/07003

The management system of

AViTA Corporation

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

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices, Annex II (excluding section IV)

For the following products

Arm Type Blood Pressure Monitor Wrist Type Blood Pressure Monitor, Infrared (Ear, Forehead, Temple) Thermometers,

Products covered and additional sites are listed in Attachment 1 of this certificate

This certificate is valid from 25 February 2020 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

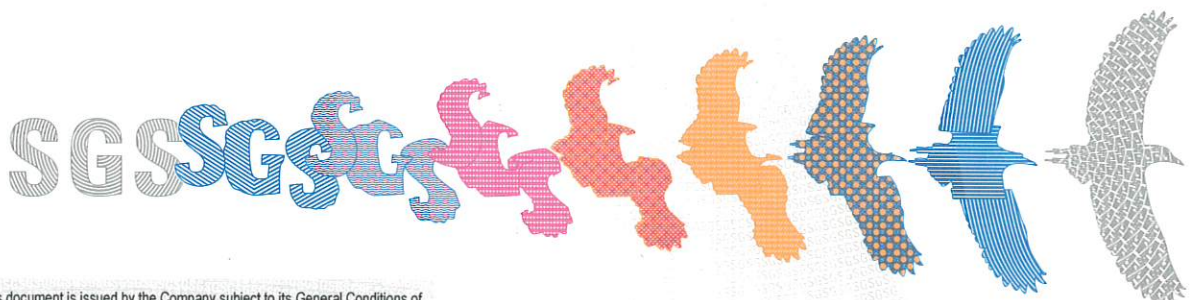
Issue 1. Certified since 26 February 2020

This certification is based on decision: FI20/07003P0

Authorised by

Seppo Vahasalo
Notified Body Manager

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Attachment 1 to SGS Fimko Ltd. EC certificate FI20/07003 Issue 1

Manufacturer	AVITA Corporation	
Address	9F, No. 78, Sec.1, Kwang-Fu Road, San-Chung District., New Taipei City, Taiwan 24158	
Other Addresses covered by the certificate	Location	Activity at the location
	AVITA (WUJIANG) Co., LTD No. 858. Jiao Tong Road, Wujang Economic Development Zone Jiangsu Province, P.R.C	Design Transfer, Purchasing, IQC, Production (TMO, parameter calibration, Assembly), IPQC, FQC, OQA, labelling, Package, Warehouse, RMA
Activity and Medical Device Product Category	93/42/EEC Annex II (excluding Section 4) Arm Type Blood Pressure Monitor Wrist Type Blood Pressure Monitor, Infrared (Ear, Forehead, Temple) Thermometers	

List of medical devices and the corresponding type/model markings with product trademarks/marketing names covered by this certificate:

Medical Device	Class	Trademark(s) and Model(s)/type(s)
Arm Type Blood Pressure Monitor	IIa	Arm Type Blood Pressure Monitor, BPM6 Series
Wrist Type Blood Pressure Monitor	IIa	Wrist Type Blood Pressure Monitor, BPM1 Series
Touch Free Infrared Thermometer	IIa	Touch Free Infrared Thermometer, NT Series
Ear/Forehead Infrared Thermometer	IIa	Ear/Forehead Infrared Thermometer, TS series