EC Declaration of Conformity

APS0-01-050

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:
Medical Device Safety Service GmbH
Schiffgraben 41
30175 Hannover, Germany

We, the manufacturer, herewith declare that the products

Product: Veroval BPW22

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

CE 0598

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

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 (without the Annex II.4) & Annex VII, of Directive 93/42/EEC

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

AViTA Corporation

Taipei County,March04, 2020
Place, date

David Huang QA Director
Legally binding signature, Function