

Application of Council Directive: 93/42/EEC – Medical Devices EEC as amended by 2007/47/EC

Manufacturer Address:

DENTSCARE LTDA - Av. Edgar Nelson Meister, 474 - Distrito Industrial - 89219-501 – Joinville – SC – Brazil - CNJP/Tax ID: 05.106.945/0001-06

Technical Responsible: Friedrich Georg Mittelstädt. CRQ: 13100147-SC

Authorized Representative:

EC/REP: Nuno Flores, Al. Bonifacio Lazaro Lozano, 3 – Piso 0 – C, 2780-125 Oeiras / Portugal, Tel: (351) 21 4439292, ec.rep@fgm.ind.br

Notify Body

BSI – Say Building, John M. Keynesplein 9, 1066, 1066 EP Amsterdam, The Netherlands -
Notified Body number: 2797

Certificate number: CE 670390 – Full Quality Assurance System

Scope: Design and manufacture of non-sterile polymer-based restorative materials, dental resin blocks, resin-based dental cements, dental adhesives and root canal fiberglass posts for dental use and associated instruments to be connected to active devices, intended for end-user sterilization, sterile synthetic absorbable calcium phosphate bone graft for dental surgery, dental implants, dental abutments and associated instruments.

We declare that the quality system for these products has been assessed according to the procedure of conformity assessment described in Annex II (excluding section 4) of Council Directive 93/42/EEC.

Allcem

Allcem Core

Allcem Veneer APS

Ambar

Ambar APS

Ambar Universal APS

Arcsys (Arcsys Frictional Implant, FGM Drills, FGM Driver, Multifunctional Healing Abutment, Burn-out CoCr coping, Abutment and Multifunctional Impression Cap)

Brava

Llis (Microhybrid+, Suprafil+)

Opallis

Opallis Flow

Opallis Lab

Opus Bulk Fill APS

Opus Bulk Fill Flow APS

Orthocem

Orthocem UV Trace

Orthobite

PrimmaArt

Vitra APS

Vitra APS Unique

White Post

Alex Miura

Quality, R&D and Regulatory Affairs Manager

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