DentsCare	**Declaration of Conformity - Medical devices** **SYNTHETIC MATERIAL FOR BONE REPLACEMENT** **Nanosynt**	

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

Manufacture Address:

DENTSCARE LTDA - Av. Edgar Nelson Meister, 474 - Distrito Industrial - 89219-501 – Joinville – SC – Brazil - CNJP/Tax ID: 05.106.945/0001-06 - Authorization of Functioning MS P5X44XY0XX28 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 698954 – Design Examination Certificate

Certificate number: CE 670390 – Full Quality Assurance System

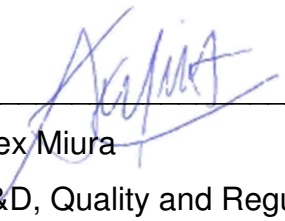
Product	**Classification**
Nanosynt	**Class III**

Product variants covered by this declaration of conformity:

Code	**Description**
20927	Nanosynt Ampoule 2x0,27cc – 200 a 500 µm
20934	Nanosynt Ampoule 2x0,27cc – 500 a 1000 µm
20938	Nanosynt Ampoule 4x0,27cc – 200 a 500 µm
20943	Nanosynt Ampoule 4x0,27cc – 500 a 1000 µm

Compliance Statement: Dentscare is exclusively responsible for this Declaration and for the compliance with all applicable standards described below, Full Quality Assurance System has been assessed according to the procedure of

conformity assessment described in Annex II of Council Directive 93/42EEC (EC Certificate 670390) and a Design Examination Certificate performed in accordance with the Council Directive 93/42EEC Annex II Section 4 (EC Certificate 698954)



Alex Miura
R&D, Quality and Regulatory Affairs Manager
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