By Royal Charter

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices, Annex II Section 4

No. **CE 698954**

Issued To: **Dentscare Ltda.**
FGM Produtos Odontológicos
Av.Edgar Nelson Meister, 474
Joinville
Santa Catarina
89219-501
Brasil

In respect of:

Nanosynt - biphasic calcium phosphate synthetic material for bone replacement

BSI has performed a design examination on the above devices in accordance with the Council Directive 93/42/EEC, Annex II Section 4. The design conforms to the requirements of this directive. For marketing of these products an additional Annex II excluding Section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2020-09-11** Date: **2020-09-11** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

EC Design-Examination Certificate

Supplementary Information to CE 698954

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Catalogue Number	Device Name	Model, Type (i.e., packaging configurations)	Intended purpose per IFU	Classification
20966	Nanosynt	Blister, 2x0,27cc - 200 a 500 µm	Reconstruction / filling of intraoral and / or maxillofacial bone defects that present at least 3 remaining bone walls; Reconstruction / filling of dental alveolus by 1 or more teeth (e.g.: after tooth removal); Maxillary sinus lifting	Class III
20967		Blister, 2x0,27cc - 500 a 1000 µm		
20965		Blister, 4x0,27cc - 200 a 500 µm		
20968		Blister, 4x0,27cc - 500 a 1000 µm		
20927		Ampoule, 2x0,27cc - 200 a 500 µm		
20934		Ampoule, 2x0,27cc - 500 a 1000 µm		
20938		Ampoule, 4x0,27cc - 200 a 500 µm		
20943		Ampoule, 4x0,27cc - 500 a 1000 µm		

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Certificate History

Date	Reference Number	Action
Current	9664384	First Issue of Nanosynt - biphasic calcium phosphate synthetic material for bone replacement.

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