

# EC Certificate - Full Quality Assurance System

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

No.

**CE 670390**

Issued To:

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

In respect of:

**Design and manufacture of non-sterile polymer-based restorative materials, dental resin blocks, resin-based dental cements, dental adhesives, root canal fiberglass posts for dental use, 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.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II 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: **2017-12-13**

Date: **2020-11-05**

Expiry Date: **2022-12-12**

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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 approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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**Brasil**

### Subcontractor:

### Service(s) supplied

Companhia Brasileira de Esterilizacao  
 Site 1  
 Av. Cruzada dos Bandeirantes  
 290 Vila Jovina  
 Cotia  
 São Paulo  
 06705-140  
 Brasil

**Radiation (Gamma Sterilization)**

HAHNENKRATT GmbH  
 Dentale Medizintechnik  
 Benzstraße 19  
 Königsbach-Stein  
 75203  
 Germany

**Manufacture**

Nuno Flores  
 Al. Bonifacio Lazaro Lozano, 3 Piso  
 Oeiras  
 2780-125  
 Portugal

**EU Representative**

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## Certificate History

Certificate No: **CE 670390**  
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Date	Reference Number	Action
13 December 2017	8707201	First issue.
26 February 2019	8864209	Traceable to NB 0086.
11 September 2020	3308137	Extension to scope to include "sterile synthetic absorbable calcium phosphate bone graft for dental surgery". Addition of subcontractor Companhia Brasileira de Esterilizacao - Site 1 for gamma sterilization.
Current	3267073	Extension to scope to include "dental implants, dental abutments and associated instruments" eIFU implementation. Correction of previous history reference number 9658632 to 3308137.

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

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