

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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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

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Date: **2020-11-05**
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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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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.

R.P.-CERTIFICATE

(ARTICLE 4.1 OF THE EUROPEAN COSMETICS REGULATION 1223/2009/EC)



G. ELKAYAM
C.E.O.

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Bld Général Wahis 53
1030 Bruxelles
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Mr. G. Elkayam CEO
Obelis sa

Annex A - List of Cosmetic Products

Annex I of Cosmetics Regulation 1223/2009/EC

#	Your Catalogue #	Product full Commercial Name (= product brand name + product function)*	Cosmetic Product Category**	Producer Company Name***
1.	Kit 7458 Mini Kit 7461 Bulk 7459 Refil 13702	Whiteness Perfect 10% Whiteness Perfect is a dentist supervised at home bleaching system, based on carbamide peroxide gel (4,15% hydrogen peroxide)	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA
2.	Kit 7462 Mini Kit 7465 Bulk 7463 Refil 13622	Whiteness Perfect 16% Whiteness Perfect is a dentist supervised at home bleaching system, based on carbamide peroxide gel (6% hydrogen peroxide)	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA
3.	Kit 6965 Bulk (50 syringes of gel) 6974 Bulk (15 syringes of gel) 6975	White Class with Calcium 5 1/2% White Class with calcium is a dentist supervised at home bleaching system, based on hydrogen peroxide gel (6% hydrogen peroxide)	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA
4.	Kit 7447 Bulk (50 syringes of gel) 7448 Bulk (15 syringes of gel) 7449	White Class with Calcium 6 % White Class with calcium is a dentist supervised at home bleaching system, based on hydrogen peroxide gel (6% hydrogen peroxide)	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA

5.	Kit 9819 Bulk (50 syringes of gel) 9796 Bulk (15 syringes of gel) 9797	White Class with Calcium 4% White Class with calcium is a dentist supervised at home bleaching system, based on hydrogen peroxide gel (4% hydrogen peroxide)	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA
6.	Mini Kit 19619 Refil 19620	WHITENESS HP AUTOMIXX 6% Whiteness HP AutoMixx 6% is a hydrogen peroxide whitening gel (6% hydrogen peroxide) for vital teeth indicated exclusively for in office use.	Oral Hygiene Products Tooth whiteners	DENTSCARE LTDA

* Please note that the names of the products mentioned in Annex A must perfectly match the ones mentioned on the label, Safety Assessment and any other referring document in the Product Information File

** The hereabove product list classification is based on the classification claim of the manufacturer and under its sole responsibility (Article 2 of the Regulation 1223/2009/EC and the CPNP manual)

*** Please list the Company that effectively makes the product on their facilities and that is the holder of the GMP

Obelis SA

Obelis s.a.

G. ELKAYAM
C.E.O.

Signature: _____

Date: 04/09/2018

Stamp: _____

OBELIS s.a. - O.E.R.P.C.
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SINCE 1988