CERTIFICATE OF MDD NOTIFICATION

Ref. No.: TP 1406-2021

Date: 11/05/2021

Order No.: MA 0717-2021N

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: BLUE DENT DENTAL

ADDRESS: RUA GERALDO GOZE, 459 13634-319 PIRASSUNUNGA, SÃO PAULO, BRAZIL

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * devices complies with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the Council Directive 93/42/EEC article 11 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical device, as stipulated here below, is/are fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical device has been completed by Obelis s.a. (O.E.A.R.C.) on the 07/05/2021 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

CLASS I MEDICAL DEVICE: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 1 DEVICE)

As of the 08/05/2021, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on this device;

- May place this device in the European Union and EEA territory,

G. ELKAYAM C.E.O

Obelis s.a. - O.E.A.R.C.
Registered Address
Bld General Wahis 53
1030 Bruxelles

Mr. G. Elkayam CEO
Obelis sa

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2015 and ISO 13485 : 2016 certified in accordance to the profession of a European Authorized Representative.

*Also applicable to Class Is and Im

** This Certificate will be automatically void if the notification is rejected by the EU Authorities or upon termination of the EAR agreement.

* This is not a CE mark and is only provided as a template for informational purposes.

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Annex A - List of Devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN / GIVD Code	Class	Rule (only for MDD)
1.	Sirona (Monocolor, Multilayer, Gum, Clear); Zirkonzahn (Monocolor, Multilayer, Gum, Clear); Amann (Monocolor, Multilayer, Gum, Clear); Wieland (Monocolor, Multilayer, Gum, Clear);	Evolux PMMA	PMMA for milling machine - Dental use	Discs and blocks in PMMA material to be milled (CAD CAM system): temporary crowns and bridges prosthesis	31783	I	5

* Annex A is part of the Agreement.

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (IVD 98/79/EC).

Obelis s.a.
Date: 11/05/2021
Stamp:
Signature:

G. ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
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