Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

EUROPEAN RESPONSIBLE PERSON CENTER – Obelis – SINCE 1988

E.A.R.-CERTIFICATE

(ARTICLE 14.2 OF THE DIRECTIVE 93/42/EEC ON MEDICAL DEVICES)

REF. NO.: TP 1405-2021

ORDER NO.: MA 0717-2021N

DATE: 11/05/2021

MANUFACTURER: Blue Dent Dental
Rua Geraldo Goze, 459 13634-319
Pirassununga, São Paulo, Brazil

FACILITIES: Blue Dent Dental
Rua Geraldo Goze, 459 13634-319
Pirassununga, São Paulo, Brazil

PRODUCT CATEGORIES: Please See Annex A - List of Devices (1 Device, 1 Page)

MODELS: Please See Annex A - List of Devices (1 Device, Page)

The European Authorized Representative Center Obelis s.a. declares that the aforementioned manufacturer has fulfilled the essential requirement of appointing a European Authorized Representative in accordance with article 14.2 of the MDD 93/42/EEC and to the terms and conditions set out in the agreement entered into force on 01/10/2020

G. ELKAYAM C.E.O.

Obelis s.a. - O.E.A.R.C.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

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.

*This certificate is not a confirmation of product notification nor an approval to place products on the market.
**This certificate will become void automatically upon termination of the EAR agreement.

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

Order No.: MA 0717-2021N
Ref No.: TP 1405-2021

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.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03