

E.A.R.-CERTIFICATE

(Article 14.2 of the Directive 93/42/EEC on Medical Devices)

ref. no.: PD 1611-2021

Order No.: MA 9944-2020

date: 03/06/2021

Manufacturer:

Facilities:

Models:

G. ELKAYAM
C.E.O.

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

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Mr. G. Elkayam CEO

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* 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

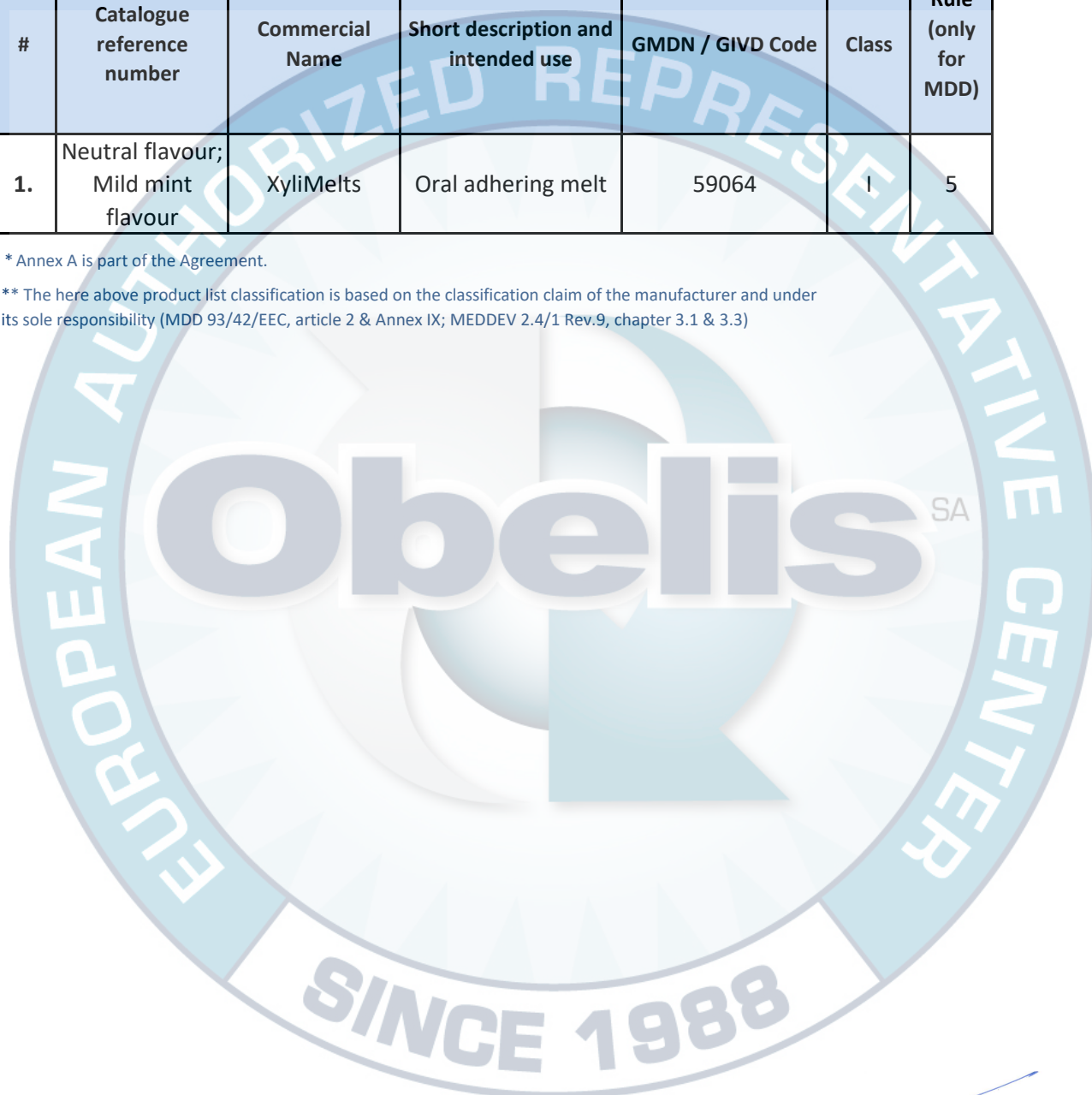
(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

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

#	Catalogue reference number	Commercial Name	Short description and intended use	GMDN / GIVD Code	Class	Rule (only for MDD)
1.	Neutral flavour; Mild mint flavour	XyliMelts	Oral adhering melt	59064	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)

**Obelis s.a.****Signature:****Stamp:****Date: 03/06/2021**

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