



# CERTIFICATE OF IVD NOTIFICATION

*G. Elkayam*  
CEO

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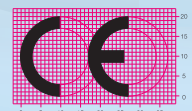
**Mr. G. Elkayam CEO**

**Obelis sa**



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Order No.: SZ 7593-2019

Ref No.: EZ 8047-2019

**Annex A - List of 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/EDMS Code	Class
1.	RED-62-16	REDx Controls HPV 16 Positive Control	Unassayed HPV 16 positive control	For IVD use as unassayed positive control in NAAT detecting HPV type 16	52766	All others
2.	RED-62-18	REDx Controls HPV 18 Positive Control	Unassayed HPV 18 positive control	For IVD use as unassayed positive control in NAAT detecting HPV type 18	52766	All others
3.	RED-62-45	REDx Controls HPV 45 Positive Control	Unassayed HPV 45 positive control	For IVD use as unassayed positive control in NAAT detecting HPV type 45	52766	All others
4.	RED-99-M1	REDx Controls HPV Negative Control	Unassayed HPV negative control	For IVD use as unassayed negative control in NAAT detecting HPV type 16, 18 and 45	52766	All others

\* 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 (IVD 98/79/EC).

**Obelis s.a.****Signature:****Date: 21.08.2019****Stamp:**

G. ELKAYAM  
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