



CERTIFICATE OF IVD NOTIFICATION

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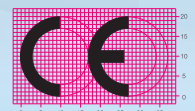
Mr. G. Elkayam CEO

Obelis sa



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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 Code	Class
1.	RED-63-01	REDx <i>Mycoplasma genitalium</i> Positive Control	Unassayed MG Positive Control	For IVD use as unassayed positive control in NAAT detecting M.genitalium	47323	All others
2	RED-99-M1	REDx STI Negative Control	Unassayed STI Negative Control	For IVD use as unassayed negative control in NAAT detecting STI	50411	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: _____

G. ELKAYAM
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Stamp:

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