

# Public Declaration for In-House devices

## Part A - Information about the manufacturing Health Institution

### Legal Entity of the Health Institution

Name	Address
Unilabs, laboratoire d'analyses médicales SA	Chemin des Perrières 2, 1296 Coppet

### List of Health Institution Sites under scope of this Public Declaration

Name	Department	Address	Contact Person
Unilabs, laboratoire d'analyses médicales SA	N/A	Chemin des Perrières 2, 1296 Coppet	Françoise Morel

### Contact Data of Responsible Person for the Legal Entity

Name	Job Title	Telephone Number	E-mail
Françoise Morel	Quality Manager	+41 79 636 75 24	Francoise.morel2@unilabs.com

### Declaration

Above mentioned Health Institution states for all tests listed in part B:

- i) The device is manufactured or modified and used in sites within the same legal entity under the scope of this Public Declaration.
- ii) The device is manufactured or modified by this Health Institution under compliant EN ISO 15189 quality management system.
- iii) The device is compliant with relevant General Safety and Performance Requirements (GSPR) as depicted in Annex I of SR 812.219 Ordinance on In Vitro Diagnostic Medical Device (IvDO) and according to Article 5 (5).
- iv) A reasoned justification is provided in case applicable General Safety and Performance Requirements are not fully met.
- v) Argumentation for use of in-house tests is documented in the quality management system, through technical file documentation.

I, the undersigned, in my capacity as Head of Medical, certify that the information given is true, accurate, present and complete to the best of my knowledge. I understand that if I have deliberately given any false information regarding any situation, I am liable against the law.

**Signed on behalf the organisation**

**Responsible for the lab name**

*(Technical Director or equivalent technical role)*

**Date**

**Signature**

Dany Mercan

**Part B – Description of the In-House devices**

**In-house Family Device Name**

Vitamins A, D, E, CoQ10, Carotenoids Determination by LC - MS

**List of assays or in-house devices within the Family**

#	In-house reference	In-house name	Device Type	Risk class	Intended Purpose	Applicable GSPR fully met?	Information on and justification for applicable GSPR that are not fully met (using the numbering as in Annex I of the IVDR/MDR)
1	4300	Retinol	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
2	3473 3478	D2+D3	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
3	4316	Alpha Tocopherol	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
4	4314	Gamma Tocopherol	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
5	3067	CoQ10	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
6	4321	Alpha Carotenoid	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
7	4320	Beta Carotenoid	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160



8	3804	Beta Cryptoxantin	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
9	3803	Lutein + Zeaxantin	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160
10	3802	Lycopene	IVD	B	FORM-IVDR-LDT-01_VIT_A_D_E_CoQ10_Carotenoids IMS 1058153	YES	FORM-IVDR-LDT-02_VIT_A_D_E_CoQ10_Carotenoids IMS 1058160