

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 <i>(Technical Director or equivalent technical role)</i>	Date	Signature
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Part B – Description of the In-House devices
In-house Family Device Name

TRACE ELEMENTS Determination by ICP - 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	8758 (Urine spot) 4358 (Plasma)	Aluminium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
2	8761 (Urine spot) 9761 (Urine 24H) 4361 (Whole blood)	Arsenic	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
3	8770 (Urine spot)	Bore	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
4	8759 (Urine spot) 9356 (Urine 24H) 4359 (Whole blood)	Cadmium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
5	8757 (Urine spot) 9354 (Urine 24H) 4355 (Whole blood)	Cobalt	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139

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					IMS 1057133		
6	8756 (Urine spot) 4356 (Whole blood)	Chrome	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
7	8750 (Urine spot) 9750 (Urine 24H) 4350 (Whole blood)	Copper	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
8	8300 (Urine spot) 9300 (Urine 24H) 3300 (Serum)	Iron	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
9	8760 (Urine spot) 9759 (Urine 24H) 4360 (Whole blood)	Mercury	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
10	8026 (Urine spot) 9358 (Urine 24H) 5026 (Plasma)	Iodine	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
11	8204 (Urine spot) 9204 (Urine 24H) 3204 (Serum) 3205 (Erythrocytes)	Magnesium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
12	8754 (Urine spot) 4354 (Whole blood)	Manganese	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
13	8771 (Urine spot) 4383 (Whole blood)	Molybdenum	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139

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					IMS 1057133		
14	8763 (Urine spot) 4368 (Whole blood)	Nickel	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
15	8764 (Urine spot) 9357 (Urine 24H) 4357 (Whole blood)	Lead	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
16	8772 (Urine spot) 4367 (Plasma)	Platinum	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
17	8753 (Urine spot) 4353 (Plasma)	Selenium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
18	8762 (Urine spot) 4370 (Whole blood)	Tin	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
19	8774 (Urine spot)	Strontium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS 2IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
20	8767 (Urine spot) 9767 (Urine 24H) 4363 (Plasma)	Thallium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
21	8773 (Urine spot)	Uranium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139

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22	8768 (Urine spot) 4377 (Plasma)	Vanadium	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139
23	8751 (Urine spot) 9351 (Urine 24H) 4351 (Plasma) 4352 (Erythrocytes)	Zinc	IVD	B	FORM-IVDR-LDT-01_TRACE_ELEMENTS IMS 1057133	YES	FORM-IVDR-LDT-02_GSPR IMS 1057139