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 médicale	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 *in vitro* Medical Device Regulation (EU) 2017/746 (IVDR) 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 Laboratory Director 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

Name of the responsible of the lab *(Technical Director or equivalent technical role)*	Date	Signature
Mattia Schmid	08-Oct-2024 | 10:10 CEST	Signed by: 255742BFF1AB4CF...

Part B – Description of the In-House devices

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	NGS Capture	NGS capture based family	IVD	C	See IMS reference: 1057554	Yes	See IMS reference: 1057630
2	NGS Amplicon	NGS amplicon based family	IVD	C	See IMS reference: 1057555	Yes	See IMS reference: 1057603
3	Sanger	Sanger sequencing family	IVD	C	See IMS reference: 1058409	Yes	See IMS reference: 1057599
4	MLPA	Multiplex Ligation-dependent Probe Amplification family	IVD	C	See IMS reference: 1057557	Yes	See IMS reference: 1057625
5	Extraction	Extraction family	IVD	C	See IMS reference: 1058267	Yes	See IMS reference: 1058269