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 Coppet	Clinical Chemistry	Chemin des Perrières 2, 1296 Coppet	H. Gzara
Unilabs Dübendorf	Clinical Chemistry	Ringstrasse 12, 8600 Dübendorf	W. Wallimann, D. Hof
Unilabs Ticino	Clinical Chemistry	Via Rovere 8, 6932 Breganzona	D. Hof
Unilabs Mittelland	Clinical Chemistry	Murtenstrasse 143A, 3008 Bern	W. Wallimann
Unilabs See-Spital Horgen	Clinical Chemistry	Asylstrasse 19, 8810 Horgen	D. Hof
Unilabs Spital Lachen	Clinical Chemistry	Oberdorfstrasse 41, 8853 Lachen	D. Hof
Unilabs Regionalspital Emmental	Clinical Chemistry	Dorfbergstrasse 10, 3550 Langnau im Emmental	W. Wallimann
Unilabs Neuchâtel	Clinical Chemistry	Rue de l'Hôpital 20, 2000 Neuchâtel	S. Jilek-Terrasse
Unilabs Lausanne	Clinical Chemistry	Rue de la Vigie 5, 1003 Lausanne	S. Jilek-Terrasse
Unilabs Valais	Clinical Chemistry	Av. De Tourbillon 5, 1950 Sion	S. Jilek-Terrasse
Unilabs Champel	Clinical Chemistry	Avenue Jules-Crosnier 8, 1206 Genève	H. Gzara

Contact Data of Responsible Person for the Legal Entity			
Name	**Job Title**	**Telephone Number**	**E-mail**
Dany Mercan	Medical director	022 716 20 00	dany.mercan@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 medical director, Switzerland, 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**
Unilabs, laboratoire d'analyses médicales SA Dany Mercan		Digitally signed by Dany Mercan Date: 2024.06.03 12:05:32 +02'00'

Part B – Description of the In-House devices

In-house Family Device Name

Clinical chemistry analyses in particular matrices or body fluids

	List of assays or in-house devices within the Family							
#	In-house reference	In-house name	Device Type	Type of in-house	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	Body fluids	Albumin, amylase, CEA, chloride, cholesterol, chylomicrons, creatinine, CRP, glucose, lactate, LDH, lipase, pancreatic amylase, potassium, proteins, rheumatoid factor, sodium, total bilirubin, triglycerides, urea, uric acid	IVD	IVD tests with modification	B	IMS1057170	Yes	not applicable