GROUP TEMPLATE

PUBLIC DECLARATION FOR IN-HOUSE DEVICES ACCORDING TO ARTICLE 5(5) OF THE IVDR AND MDR

WRITTEN BY

Name	Role	Date	Signature
Marta Montilla	Group IVDR Manager		

APPROVED BY

Name	Role	Date	Signature
Catherine Derrien	Head of Quality Assurance and Regulatory Affairs		

Public Declaration for In-House devices

Part A - Information about the manufacturing Health Institution

Legal Entity of the Health Institution

Name	Address
Unilabs NL	Koningsplein 1, Enschede, NL

List of Health Institution Sites under scope of this Public Declaration

Name	Department	Address	Contact Person
Unilabs NL	East, former Medlon	Koningsplein 1, Enschede, NL	Dr. C.J.A. Doelman, MBA

Contact Data of Responsible Person for the Legal Entity

Name	Job Title	Telephone Number	E-mail
Dr. C. Pronk-Admiraal, MBA	Head of Medical	+31622487929	Claudia.pronk@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 Head of Medical and legally responsible, 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
Dr. C. Pronk-Admiraal, MBA	May 24th, 2024	

OPTION A – TECHNICAL FILE PER FAMILY – FAMILY DECLARATION (GEN, PATH and IVD):

Part B – Description of the In-House devices

In-house Family Device Name

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	67869	Spectrofotometrische analyse van liquor	IVD	C	Liquor analyse op bloedpigmenten	Yes	
2	67719	Sporenmetalen en zware metalen mbv ICPMS	IVD	C	Analyse van zware metalen	Yes	
3	67694	Heemsynthese metabolieten mbv LCMS	IVD	C	Verdenking op porfyrieen	Yes	
4	67685	Vet en vrije vetzuren in feces mbv FT-IR	IVD	C	Pancreasinsufficientie	Yes	
5	67654	Suikerabsorptietest	IVD	C	Analyse van darmpermeabiliteit	Yes	
6	67626	Niersteenanalyse mbv Infraroodspectrometrie	IVD	C	Analyse van nierstenen	Yes	
7	67625	Homocysteine in plasma	IVD	C	Analyse	Yes	
8	67590	Vitamine C in plasma	IVD	C	Analyse	Yes	
9	67589	Steenanalyse in urine, meting van citraat, glycolzuur, oxolaat, cystine en oxoproline	IVD	C	Analyse van nierstenen	Yes	
10	67469	Serotonine in bloedplaatjes	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes	

11	67468	HVA, VMA en 5-HIAA in urine	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes
12	67467	Metanefrines in urine	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes
13	67462	Dexamethason	IVD	C	Diagnostiek van Cushing	Yes
14	67402	Melatonine in Speeksel	IVD	C	Diagnostiek van slaapstoornissen	Yes
15	67371	Steroidprofiel in bloed	IVD	C	Diagnostiek	Yes
16	67367	DNA analyse by myeloide aandoeningen	IVD	C	Diagnostiek van hemato-oncologische afwijkingen	Yes
17	67318	Mutatieanalyse van Hb-pathieen	IVD	C	Diagnostiek bij verdenking Hb-pathieen	Yes
18	67316	Conventionele PCR voor alfa-thalassemie, FLT3-ITD en FLT3-TKD	IVD	C	Diagnostiek bij hematologische afwijkingen	Yes
19	67315	HLA B27-genotypering	IVD	C	Diagnostiek van ziekte van Bechterew	Yes
20	67314	CYP, DPYD, Lactase, Factor II, Factor V genotypering	IVD	C	Diagnostiek bij trombose, voorspellen werking geneesmiddelen	Yes
21	67313	Translocaties bij hemologische maligniteiten mbv RQ-PCR	IVD	C	Diagnostiek van hematologische afwijkingen	Yes
22	67269	Trombocytenaggregatie-testen	IVD	C	Diagnostiek bij stollingsstoornissen	Yes
23	67268	Flowcytometrische analyse van cellen in bloed, beenmerg of andere lichaamsvochten	IVD	C	Diagnostiek van hematologische aandoeningen	Yes
24	67267	Cytochemische kleuringen op bloed, beenmerg en andere lichaamsvochten	IVD	C	Diagnostiek van hematologische aandoeningen	Yes
25	67242	Vitamine B2	IVD	C	Verdenking op deficienties	Yes

OPTION B – TECHNICAL FILE PER IN-HOUSE (IVD):
One Public Declaration by listing all the in-house tests within the same legal entity / site (if different QMS)

Part B – Description of the In-House devices

List of in-house devices within the health institution

#	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			(IVD or MD)	(A, B, C or D)	Refer to the corresponding form	Yes or No	Refer to the corresponding form
2							
...							

** If desired, the table can include one column indicating which type of in-house is involved (eg developed in-house, research use only test or IVD test with modifications).*