

Public Declaration for In-House devices

Part A - Information about the manufacturing Health Institution

Legal Entity of the Health Institution

Name	Address
Unilabs Diagnostics b.v.	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	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 <i>(Technical Director or equivalent technical role)</i>	Date	Signature
Dr. C. Pronk-Admiraal, MBA	May 30th, 2024	

Part B – Description of the In-House devices
In-house Family Device Name

Sporenelementen en zware metalen met behulp van ICPMS

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	67719	Aluminium	IVD	C	Intoxication	Yes	N/A
2	67719	Cadmium	IVD	C	Intoxication	Yes	N/A
3	67719	Lood	IVD	C	Intoxication	Yes	N/A
4	67719	Thallium	IVD	C	Intoxication	Yes	N/A
5	67719	Kwik	IVD	C	Intoxication	Yes	N/A
6	67719	Magnesium	IVD	C	Intoxication	Yes	N/A
7	67719	Chroom	IVD	C	Intoxication	Yes	N/A
8	67719	Cobalt	IVD	C	Intoxication	Yes	N/A
9	67719	Seleen	IVD	C	Intoxication	Yes	N/A
10	67719	Koper	IVD	C	Intoxication	Yes	N/A
11	67719	Zink	IVD	C	Intoxication	Yes	N/A
12	67719	Arseen	IVD	C	Intoxication	Yes	N/A
13	67719	Mangaan	IVD	C	Intoxication	Yes	N/A
14	67719	Nikkel	IVD	C	Intoxication	Yes	N/A
15	67719	IJzer	IVD	C	Intoxication	Yes	N/A
16	67719	Barium	IVD	C	Intoxication	Yes	N/A
17	67719	Stontium	IVD	C	Intoxication	Yes	N/A
18	67719	Molybdeen	IVD	C	Intoxication	Yes	N/A

Part B – Description of the In-House devices

In-house Family Device Name

Heemsynthese metabolieten

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	67694	Delta-aminolevulinezuur	IVD	C	Diagnostiek van porfyrieën	Yes	N/A
2	67694	Porfobilinogeen	IVD	C	Diagnostiek van porfyrieën	Yes	N/A
3	67694	Porfyrene profiel	IVD	C	Diagnostiek van porfyrieën	Yes	N/A

Part B – Description of the In-House devices
In-house Family Device Name

Steenanalyse in urine met behulp van 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	67589	Citraat	IVD	C	Diagnostiek bij nierstenen	Yes	N/A
2	67589	Glycolzuur	IVD	C	Diagnostiek bij nierstenen	Yes	N/A
3	67589	Oxaalzuur	IVD	C	Diagnostiek bij nierstenen	Yes	N/A
4	67589	Cystine	IVD	C	Diagnostiek bij nierstenen	Yes	N/A
5	67589	Oxoproline	IVD	C	Diagnostiek bij nierstenen	Yes	N/A

Part B – Description of the In-House devices
In-house Family Device Name

Genotypering met behulp van RT-PCR

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	67314	CYP2D6*3,*4,*6,*41,*5	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
2	67314	CYP2C9*2, *3	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
3	67314	CYP3A4*22	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
4	67314	CYP1A2*1f	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
5	67314	CYP2B6*6	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
6	67314	CYP3A5*3	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
7	67314	HLADQ2/DQ8	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A
8	67314	DPYD genotypering	IVD	C	Therapeutic monitoring (farmacogenetica)	Yes	N/A

Part B – Description of the In-House devices

In-house Family Device Name

Nextgeneration Sequencing

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	67367	NGS Myeloid panel	IVD	C	Diagnostische en Prognostische criteria voor Myeloide maligniteiten	Yes	N/A

Part B – Description of the In-House devices
In-house Family Device Name

Sequentieanalyse voor hemoglobinopathieën

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	67318	Alfa-globuline genen	IVD	C	Diagnostiek op verdenking hemoglobinopathie en/of thalassemie	Yes	N/A
2	67318	Beta-globuline genen	IVD	C	Diagnostiek op verdenking hemoglobinopathie en/of thalassemie	Yes	N/A

Part B – Description of the In-House devices
In-house Family Device Name

Flowcytometrie; alle testen zijn panel van diverse monoclonalen

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1	67268	Fetal Cell Count Kit van IQ-products (REF IQP-363)	IVD	C	Kleihauertest	Yes	N/A
2	67268	Beta Mark TCR Vβ Repertoire Kit van Beckman Coulter (REF IM3497)	IVD	C	Clonaliteit T-cel maligniteiten	Yes	N/A
3	67268	Stem-Kit van Beckman Coulter (REF 3630)	IVD	C	CD34 (PB - Aferese-recovery)	Yes	N/A
4	67268	CD45, CD10, 4CD19 en CD20	IVD	C	Rituximab monitoring	Yes	N/A
5	67268	CD1a, CD3, CD4, CD7, CD8, CD16,	IVD	C	Bronchoalveolaire lavage	Yes	N/A

List of assays or in-house devices within the Family

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		CD19, CD33, CD38, CD45, CD56, CD138, HLADR					
6	67268	CD14, CD15, CD24, CD45, CD59, CD64, CD157, CD235a, FLAER	IVD	C	Paroxysmale Nachtelijke Hemoglobinurie	Yes	N/A
7	67268	CD3, CD4, CD7, CD8, CD19, CD45, CD56, CD103, TCR- $\gamma\delta$	IVD	C	Darmbiopt	Yes	N/A
8	67268	CD2, CD14, CD15, CD25, CD30, CD33, CD45, CD117	IVD	C	Mestcel-analyse	Yes	N/A
9	67268	CD1a, CD2, CD3, CD4, CD5, CD7, CD8, CD10, CD11b,	IVD	C	Immunofenotypering van lymfatische en myeloide maligniteiten	Yes	N/A

List of assays or in-house devices within the Family

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		CD11c, CD13, CD14, CD15, CD16, CD19, CD20, CD22, CD23, CD24, CD25, CD27, CD30, CD31, CD33, CD34, CD36, CD38, CD38ME, CD39, CD41, CD43, CD45, CD45RA, CD49d, CD52, CD56, CD61, CD62L, CD64, CD71, CD73, CD79a, CD79b, CD81, CD94, CD95, CD103,					

List of assays or in-house devices within the Family

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		CD105, CD117, CD123, CD133, CD138, CD185, CD200, CD235a, CD303, CD304, CD305, Draq-7, FMC7, Granz-B, HLADR, IgA, IgD, IgG, IgM, Kappa, KORSA, Lambda, MPO, Perforin, TCL-1, TCR $\alpha\beta$, TCR $\gamma\delta$, TDT, TRBC-1 en VS38c					

Part B – Description of the In-House devices
In-house Family Device Name

Cytochemische kleuringen van cellen

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	67267	May-Grunwald-Giemsa kleuring	IVD	C	Beoordeling bloedcellen	Yes	N/A
2	67267	Sudan Black kleuring	IVD	C	Diagnostiek van Acute Myeloide Leukemieën	Yes	N/A
3	67267	IJzerkleuring	IVD	C	Diagnostiek van IJzerstoornissen	Yes	N/A
4	67267	Esterase kleuring	IVD	C	Diagnostiek van Acute Myeloide Leukemieën	Yes	N/A
5	67267	Toluidine blauw kleuring	IVD	C	Diagnostiek van Mastocytose	Yes	N/A

Part B – Description of the In-House devices
List of in-house devices within the health institution

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1	67869	Spectrofotometrische analyse van liquor	IVD	C	Liquor analyse op bloedpigmenten	Yes	N/A
2	67685	Vet en vrije vetzuren in feces mbv FT-IR	IVD	C	Pancreasinsufficiëntie	Yes	N/A
3	67654	Suikerabsorptietest	IVD	C	Analyse van darmpermeabiliteit	Yes	N/A
4	67626	Niersteenanalyse mbv Infraroodspectrometrie	IVD	C	Analyse van nierstenen	Yes	N/A
5	67625	Homocysteïne in plasma	IVD	C	Analyse	Yes	N/A
6	67590	Vitamine C in plasma	IVD	C	Analyse	Yes	N/A
7	67469	Serotonine in bloedplaatjes	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes	N/A
8	67468	HVA, VMA en 5-HIAA in urine	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes	N/A
9	67467	Metanefrines in urine	IVD	C	Screening op en vervolgen van Feochromocytomen	Yes	N/A
10	67462	Dexamethason	IVD	C	Diagnostiek van Cushing	Yes	N/A
11	67402	Melatonine in Speeksel	IVD	C	Diagnostiek van slaapstoornissen	Yes	N/A
12	67371	Steroidprofiel in bloed	IVD	C	Diagnostiek	Yes	N/A
13	67315	HLA B27-genotypering	IVD	C	Diagnostiek van ziekte van Bechterew	Yes	N/A

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14	67269	Trombocytenaggregatie-testen	IVD	C	Diagnostiek bij stollingsstoornissen	Yes	N/A
15	67242	Vitamine B2	IVD	C	Verdenking op deficiënties	Yes	N/A
16	68127	Duffy genotypering	IVD	D	Bloedgroep Duffy typering	Yes	N/A