Public Declaration for In-House devices

Part A - Information about the manufacturing Health Institution

Legal Entity of the Health Institution

Name	Address
Unilabs A/S	Unilabs Pharma Solutions Copenhagen Nygaardsvej 32, 2100 Copenhagen O, Denmark

List of Health Institution Sites under scope of this Public Declaration

Name	Department	Address	Contact Person
Unilabs A/S	Unilabs Pharma Solutions Copenhagen	Nygaardsvej 32, 2100 Copenhagen O, Denmark	Anette Østergaard

Contact Data of Responsible Person for the Legal Entity

Name	Job Title	Telephone Number	E-mail
Anette Østergaard	Head of Site, Unilabs Pharma Solutions Copenhagen	+45 23 22 31 36	anette.ostergaard@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* Diagnostic 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 site, Unilabs Copenhagen 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	Date	Signature
Head of Site, Unilabs A/S Copenhagen Anette Østergaard	2026-10-19	

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	C5011	FIX inhibitor	IVD	C	TF_FIX inhibitor	Yes	N/A