# Public Declaration for In-House devices

## Part A - Information about the manufacturing Health Institution

### Legal Entity of the Health Institution

| Name | Address |
|---|---|
| Unilabs St. Gallen AG | Walenbüchelstrasse 1, 9000 St. Gallen |

### List of Health Institution Sites under scope of this Public Declaration

| Name | Department | Address | Contact Person |
|---|---|---|---|
| Unilabs St. Gallen AG | Hematology | Walenbüchelstrasse 1, 9000 St. Gallen | I. Steiner |

### Contact Data of Responsible Person for the Legal Entity

| Name | Job Title | Telephone Number | E-mail |
|---|---|---|---|
| Zorica Stjepanovic | Responsible Technical Organisation Prox Lab St. Gallen | 058 864 55 22 | zorica.stjepanovic@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 Routine CoE 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** |
| Head of Routine CoE<br>Iris Steiner | 13.06.2024 | I. Steiner |

## 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 | Measurement of Thrombocytes in Sodium-Citrate whole blood | TC from Citrate | IVD | B | IMS1057243 | Yes | Not applicable |