**Declaration of compliance with standard ISO 15 189:2022 requirements**

Applicant: Name (Business name)

Address incl. postcode, Company registration No

Name of workplace No 1.: Address incl. postcode

Name of workplace No 1.: Address incl. postcode

Certificate of accreditation No:      *\*) specify only in case of application for accreditation, reassessment or extension*

| **Standard clause** | **Name of clause** | **Description of Compliance – reference to the articles of the relevant documents \*)** |
| --- | --- | --- |
| **4** | **General requirements** | **-** |
| 4.1 | Impartiality |  |
| 4.2 | Confidentiality |  |
| *4.2.1* | *Management of information* |  |
| *4.2.2* | *Release of information* |  |
| *4.2.3* | Personnel responsibility |  |
| 4.3 | Requirements regarding patients |  |
| **5** | **Structural and governance requirements** | **-** |
| 5.1 | Legal entity |  |
| 5.2 | Laboratory director | **-** |
| *5.2.1* | *Laboratory director competence* |  |
| *5.2.2* | *Laboratory director responsibilities* |  |
| *5.2.3* | *Delegation of duties* |  |
| 5.3 | Laboratory activities | **-** |
| *5.3.1* | *General* |  |
| *5.3.2* | *Conformance with requirements* |  |
| *5.3.3* | *Advisory activities* |  |
| 5.4 | Structure and authority | **-** |
| *5.4.1* | *General* |  |
| *5.4.2* | *Quality management* |  |
| 5.5 | Objectives and policies |  |
| 5.6 | Risk management |  |
| **6** | **Resource requirements** | **-** |
| 6.1 | General | **-** |
| 6.2 | Personnel | - |
| *6.2.1* | *General* |  |
| *6.2.2* | *Competence requirements* |  |
| *6.2.3* | *Authorization* |  |
| *6.2.4* | *Continuing education and professional development* |  |
| *6.2.5* | *Personnel records* |  |
| 6.3 | Facilities and environmental conditions | - |
| *6.3.1* | *General* |  |
| *6.3.2* | *Facility controls* |  |
| *6.3.3* | *Storage facilities* |  |
| *6.3.4* | *Personnel facilities* |  |
| *6.3.5* | *Sample collection facilities* |  |
| 6.4 | Equipment | - |
| *6.4.1* | *General* |  |
| *6.4.2* | *Equipment requirements* |  |
| *6.4.3* | *Equipment acceptance procedure* |  |
| *6.4.4* | *Equipment instructions for use* |  |
| *6.4.5* | *Equipment maintenance and repair* |  |
| *6.4.6* | *Equipment adverse incident reporting* |  |
| *6.4.7* | *Equipment records* |  |
| 6.5 | Equipment calibration and metrological traceability | - |
| *6.5.1* | *General* |  |
| *6.5.2* | *Equipment calibration* |  |
| *6.5.3* | *Metrological traceability of measurement results* |  |
| 6.6 | Reagents and consumables | - |
| *6.6.1* | *General* |  |
| *6.6.2* | *Reagent and consumables – Receipt and storage* |  |
| *6.6.3* | *Reagent and consumables – Acceptance testing* |  |
| *6.6.4* | *Reagent and consumables – Inventory management* |  |
| *6.6.5* | *Reagent and consumables – Instructions for use* |  |
| *6.6.6* | *Reagent and consumables – Adverse incident reporting* |  |
| *6.6.7* | *Reagent and consumables – Records* |  |
| 6.7 | Service agreements | - |
| *6.7.1* | *Agreements with laboratory users* |  |
| *6.7.2* | *Agreements with POCT operators* |  |
| 6.8 | Externally provided products and services | - |
| *6.8.1* | *General* |  |
| *6.8.2* | *Referral laboratories and consultants* |  |
| *6.8.3* | *Review and approval of externally provided products and services* |  |
| **7** | **Process requirements** | - |
| 7.1 | General |  |
| 7.2 | Pre-examination processes | - |
| *7.2.1* | *General* |  |
| *7.2.2* | *Laboratory information for patients and users* |  |
| *7.2.3* | *Requests for providing laboratory examinations* | - |
| *7.2.3.1* | *General* |  |
| *7.2.3.2* | *Oral requests* |  |
| *7.2.4* | *Primary sample collection and handling* | - |
| *7.2.4.1* | *General* |  |
| *7.2.4.2* | *Information for pre-collection activities* |  |
| *7.2.4.3* | *Patient consent* |  |
| *7.2.4.4* | *Instructions for collection activities* |  |
| *7.2.5* | *Sample transportation* |  |
| *7.2.6* | *Sample receipt* | - |
| *7.2.6.1* | *Sample receipt procedure* |  |
| *7.2.6.2* | *Sample acceptance exceptions* |  |
| *7.2.7* | *Pre-examination handling, preparation, and storage* | - |
| *7.2.7.1* | *Sample protection* |  |
| *7.2.7.2* | *Criteria for additional examination requests* |  |
| *7.2.7.3* | *Sample stability* |  |
| 7.3 | Examination processes | - |
| *7.3.1* | *General* |  |
| *7.3.2* | *Verification of examination methods* |  |
| *7.3.3* | *Validation of examination methods* |  |
| *7.3.4* | *Evaluation of measurement uncertainty (MU)* |  |
| *7.3.5* | *Biological reference intervals and clinical decision limits* |  |
| *7.3.6* | *Documentation of examination procedures* |  |
| *7.3.7* | *Ensuring the validity of examination results* | - |
| *7.3.7.1* | *General* |  |
| *7.3.7.2* | *Internal quality control (IQC)* |  |
| *7.3.7.3* | *External quality assessment (EQA)* |  |
| *7.3.7.4* | *Comparability of examination results* |  |
| 7.4 | Post-examination processes | - |
| *7.4.1* | *Reporting of results* | - |
| *7.4.1.1* | *General* |  |
| *7.4.1.2* | *Result review and release* |  |
| *7.4.1.3* | *Critical result reports* |  |
| *7.4.1.4* | *Special considerations for results* |  |
| *7.4.1.5* | *Automated selection, review, release and reporting of results* |  |
| *7.4.1.6* | *Requirements for reports* |  |
| *7.4.1.7* | *Additional information for reports* |  |
| *7.4.1.8* | *Amendments to reported results* |  |
| *7.4.2* | *Post-examination handling of samples* |  |
| 7.5 | Nonconforming work |  |
| 7.6 | Control of data and information management | - |
| *7.6.1* | *General* |  |
| *7.6.2* | *Authorities and responsibilities for information management* |  |
| *7.6.3* | *Information systems management* |  |
| *7.6.4* | *Downtime plans* |  |
| *7.6.5* | *Off site management* |  |
| 7.7 | Complaints | - |
| *7.7.1* | *Process* |  |
| *7.7.2* | *Receipt of complaint* |  |
| *7.7.3* | *Resolution of complaint* |  |
| 7.8 | Continuity and emergency preparedness planning |  |
| **8** | **Management system requirements** | - |
| 8.1 | General requirements | - |
| *8.1.1* | *General* |  |
| *8.1.2* | *Fulfilment of management system requirements* |  |
| *8.1.3* | *Management system awareness* |  |
| 8.2 | Management system documentation | - |
| *8.2.1* | *General* |  |
| *8.2.2* | *Competence and quality* |  |
| *8.2.3* | *Evidence of commitment* |  |
| *8.2.4* | *Documentation* |  |
| *8.2.5* | *Personnel access* |  |
| 8.3 | Control of management system documents | - |
| *8.3.1* | *General* |  |
| *8.3.2* | *Control of documents* |  |
| 8.4 | Control of records | - |
| *8.4.1* | *Creation of records* |  |
| *8.4.2* | *Amendment of records* |  |
| *8.4.3* | *Retention of records* |  |
| 8.5 | Actions to address risks and opportunities for improvement | - |
| *8.5.1* | *Identification of risks and opportunities for improvement* |  |
| *8.5.2* | *Acting on risks and opportunities for improvement* |  |
| 8.6 | Improvement | - |
| *8.6.1* | *Continual improvement* |  |
| *8.6.2* | *Laboratory patients, users, and personnel feedback* |  |
| 8.7 | Nonconformities and corrective actions | - |
| 8.7.1 | *Actions when nonconformity occurs* |  |
| 8.7.2 | *Corrective action effectiveness* |  |
| 8.7.3 | *Records of nonconformities and corrective actions* |  |
| 8.8 | Evaluations | - |
| *8.8.1* | *General* |  |
| *8.8.2* | *Quality indicators* |  |
| *8.8.3* | *Internal audits* | - |
| *8.8.3.1* | - |  |
| *8.8.3.2* | - |  |
| 8.9 | Management reviews | - |
| *8.9.1* | *General* |  |
| *8.9.2* | *Review input* |  |
| *8.9.3* | *Review output* |  |

\*) Upload to AIS all documents you refer to AIS.

I declare the data presented in Annex OA 3-2 to be true and correct.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Date: |  | Name and surname: |  | |
| Post: | |  | |