**Declaration of compliance with standard ISO 15 189:2012 requirements**

Applicant: Name (Business name)

Address incl. postcode, Company registration No

Name of workplace No 1.: Address incl. postcode

Name of workplace No 2.: Address incl. postcode

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

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| | **Standard clause** | | **Name of the clause** | | **Description of Compliance - reference to the articles of the relevant documents \*\*)** | | | --- | --- | --- | --- | --- | --- | | **4.1** | | **Organization and management responsibility** | | **-** | | | 4.1.1 | | Organization | | **-** | | | *4.1.1.1* | | *General* | |  | | | *4.1.1.2* | | *Legal entity* | |  | | | *4.1.1.3* | | *Ethical conduct* | |  | | | *4.1.1.4* | | *Laboratory director* | |  | | | 4.1.2 | | Management responsibility | | **-** | | | *4.1.2.1* | | *Management commitment* | |  | | | *4.1.2.2* | | *Needs of users* | |  | | | *4.1.2.3* | | *Quality policy* | |  | | | *4.1.2.4* | | *Quality objectives and planning* | |  | | | *4.1.2.5* | | *Responsibility, authority and interrelationships* | |  | | | *4.1.2.6* | | *Communication* | |  | | | *4.1.2.7* | | *Quality manager* | |  | | | **4.2** | | **Quality management system** | | **-** | | | 4.2.1 | | General requirements | |  | | | 4.2.2 | | Documentation requirements | |  | | | *4.2.2.1* | | *General* | | **-** | | | *4.2.2.2* | | *Quality manual* | |  | | | **4.3** | | **Document control** | |  | | | **4.4** | | **Service agreements** | |  | | | 4.4.1 | | Establishment of service agreements | |  | | | 4.4.2 | | Review of service agreements | |  | | | **4.5** | | **Examination by referral laboratories** | | **-** | | | 4.5.1 | | Selecting and evaluating referral laboratories and consultants | |  | | | 4.5.2 | | Provision of examination results | |  | | | **4.6** | | **External services and supplies** | |  | | | **4.7** | | **Advisory services** | |  | | | **4.8** | | **Resolution of complaints** | |  | | | **4.9** | | **Identification and control of nonconformities** | |  | | | **4.10** | | **Corrective action** | |  | | | **4.11** | | **Preventive action** | |  | | | **4.12** | | **Continual improvement** | |  | | | **4.13** | | **Control of records** | |  | | | **4.14** | | **Evaluation and audits** | | **-** | | | 4.14.1 | | General | |  | | | 4.14.2 | | Periodic review of requests, and suitability of procedures and sample requirements | |  | | | 4.14.3 | | Assessment of user feedback | |  | | | 4.14.4 | | Staff suggestions | |  | | | 4.14.5 | | Internal audit | |  | | | 4.14.6 | | Risk management | |  | | | 4.14.7 | | Quality indicators | |  | | | 4.14.8 | | Reviews by external organizations | |  | | | **4.15** | | **Management review** | | **-** | | | 4.15.1 | | General | |  | | | 4.15.2 | | Review input | |  | | | 4.15.3 | | Review activities | |  | | | 4.15.4 | | Review output | |  | | |  | |  | |  | |  | **Standard clause** | **Name of the clause** | **Description of Compliance - reference to the articles of the relevant documents \*\*)** | | --- | --- | --- | | **5.1** | **Personnel** |  | | 5.1.1 | General |  | | 5.1.2 | Personnel qualifications |  | | 5.1.3 | Job descriptions |  | | 5.1.4 | Personnel introduction to the organizational environment |  | | 5.1.5 | Training |  | | 5.1.6 | Competence assessment |  | | 5.1.7 | Reviews of staff performance |  | | 5.1.8 | Continuing education and professional development |  | | 5.1.9 | Personnel records |  | | **5.2** | **Accommodation and environmental conditions** |  | | 5.2.1 | General |  | | 5.2.2 | Laboratory and office facilities |  | | 5.2.3 | Storage facilities |  | | 5.2.4 | Staff facilities |  | | 5.2.5 | Patient sample collection facilities |  | | 5.2.6 | Facility maintenance and environmental conditions |  | | **5.3** | **Laboratory equipment, reagents, and consumables** |  | | 5.3.1 | Equipment |  | | *5.3.1.1* | *General* |  | | *5.3.1.2* | *Equipment acceptance testing* |  | | *5.3.1.3* | *Equipment instructions for use* |  | | *5.3.1.4* | *Equipment calibration and metrological traceability* |  | | *5.3.1.5* | *Equipment maintenance and repair* |  | | *5.3.1.6* | *Equipment adverse incident reporting* |  | | *5.3.1.7* | *Equipment records* |  | | 5.3.2 | Reagents and consumables |  | | *5.3.2.1* | *General* |  | | *5.3.2.2* | *Reagents and consumables — Reception and storage* |  | | *5.3.2.3* | *Reagents and consumables — Acceptance testing* |  | | *5.3.2.4* | *Reagents and consumables — Inventory management* |  | | *5.3.2.5* | *Reagents and consumables — Instructions for use* |  | | *5.3.2.6* | *Reagents and consumables — Adverse incident reporting* |  | | *5.3.2.7* | *Reagents and consumables — Records* |  | | **5.4** | **Pre-examination processes** |  | | 5.4.1 | General |  | | 5.4.2 | Information for patients and users |  | | 5.4.3 | Request form information |  | | 5.4.4 | Primary sample collection and handling |  | | *5.4.4.1* | *General* |  | | *5.4.4.2* | *Instructions for pre-collection activities* |  | | *5.4.4.3* | *Instructions for collection activities* |  | | 5.4.5 | Sample transportation |  | | 5.4.6 | Sample reception |  | | 5.4.7 | Pre-examination handling, preparation and storage |  | | **5.5** | **Examination processes** |  | | 5.5.1 | Selection, verification and validation of examination procedures | | *5.5.1.1* | *General* |  | | *5.5.1.2* | *Verification of examination procedures* |  | | *5.5.1.3* | *Validation of examination procedures* |  | | *5.5.1.4* | *Measurement uncertainty of measured quantity values* |  | | 5.5.2 | Biological reference intervals or clinical decision values |  | | 5.5.3 | Documentation of examination procedures |  | | **5.6** | **Ensuring quality of examination results** |  | | 5.6.1 | General | | 5.6.2 | Quality control |  | | *5.6.2.1* | *General* |  | | *5.6.2.2* | *Quality control materials* |  | | *5.6.2.3* | *Quality control data* |  | | 5.6.3 | Interlaboratory comparisons |  | | *5.6.3.1* | *Participation* |  | | *5.6.3.2* | *Alternative approaches* |  | | *5.6.3.3* | *Analysis of interlaboratory comparison samples* |  | | *5.6.3.4* | *Evaluation of laboratory performance* |  | | 5.6.4 | Comparability of examination results |  | | **5.7** | **Post-examination processes** |  | | 5.7.1 | Review of results |  | | 5.7.2 | Storage, retention and disposal of clinical samples |  | | **5.8** | **Reporting of results** |  | | 5.8.1 | General |  | | 5.8.2 | Report attributes |  | | 5.8.3 | Report content |  | | **5.9** | **Release of results** |  | | 5.9.1 | General |  | | 5.9.2 | Automated selection and reporting of results |  | | 5.9.3 | Revised reports |  | | **5.10** | **Laboratory information management** |  | | 5.10.1 | General |  | | 5.10.2 | Authorities and responsibility |  | | 5.10.3 | Information system management |  | | | | | |  |

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

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

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