SCOPE OF ACCREDITATION

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 of reassessment or extension*

**Specification of medical laboratory activities for which accreditation is required**

|  |  |  |
| --- | --- | --- |
| **Laboratory:** | **with fixed scope** | **with flexible scope** |
|  |  |  |

(fixed scope)

| **Item** | **Object of examination** | | **Established method** | | **Other specifications**  **(range, uncertainty, purpose, equipment, etc.)** |
| --- | --- | --- | --- | --- | --- |
| **Biological material/**  **matrix** | **Analyte/**  **Parameter** | **Principe** | **Identification of method** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

|  |
| --- |
| REMARKS: |

*In the column „Other specifications“ important specifications which by their nature do not belong to the previous columns are given. Guidance how to fill in table see in MSA -L/01 –Tab. A3-1*

#### *Fill in only in the case of a laboratory with flexible scope which is competent to develop new methods*

**(flexible scope with competence to develop new methods)**

| **Item** | **Object of examination** | | **Established method** | | **Application field** | **Other specifications**  **(range, uncertainty, purpose, equipment, etc.)** |
| --- | --- | --- | --- | --- | --- | --- |
| **Biological material/**  **matrix** | **Analyte/**  **Parameter** | **Principe** | **Identification of method** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

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| --- |
| REMARKS:: |
| **To mark the required scope of flexibility (in case the CAB requests a flexible scope of accreditation):**  The laboratory may modify and validate those test methods in the accreditation field, while maintaining the measurement principle.  Flexibility does not apply to changing the principle of the methods used in a given flexible scope.  **o** The laboratory keeps an up-to-date list of all test methods with a flexible scope of accreditation on the  [www......](http://www.cab.sk/flexibilna-akreditacia/) (CAB completes the link to the website)  The principle of flexibility can be used by the laboratory within the framework of:  **o** materials/matrices,  **o** parameters,  **o** techniques,  **o** equipment  **o** methods  **o** procedures  used for the examination |

*It should be clearly stated in the column „Other specifications“, which tests (indicator, parameter, analyte)* *the laboratory will be able to modify and validate during the validity of the accreditation.*

*Guidance how to fill in table see in MSA -L/01 –Tab. A3-2*

***To be completed only in the case of laboratory with flexible scope***

**Personnel competent to modify and validate methods/develop new methods during the validity of the accreditation**

| **First and last name, titles** | **Competence to modify, develop and validate methods -**  **- item in the specification of activities No.** |
| --- | --- |
|  |  |
|  |  |
|  |  |

*Instruction for completing the table see MSA -L/01 – Tab. A3-3.*

**Sampling**

|  |  |  |
| --- | --- | --- |
| **Laboratory:** | **with fixed scope** | **with flexible scope** |
|  |  |  |

| **Item** | **Object** | | | **Established method** | | **Other specifications** |
| --- | --- | --- | --- | --- | --- | --- |
| **Biological material/ matrix** | **Analyte/**  **parameter** | **Place of sampling** | **Principle** | **Identification** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

|  |
| --- |
| REMARKS: |

*The specification in this area of activity of the medical laboratory is filled in by the laboratory, which, in addition to testing, also takes samples of biological material.*

*Instruction for completing the table see MSA -L/01 – Tab. A3-4.*

I declare the data presented in Annex OA 3-1 is true and correct.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Date: |  | Signature: |  | | |
| Name and surname: | | |  |
| Function: | |  | |