**Declaration of compliance with requirements of EN ISO/IEC 17029: 2019, EN ISO 14065: 2021 Standard and Commission Implementing Regulation (EU) 2018/2067 as amended by Commission Implementing Regulation (EU) 2020/2084 (further on only “AVR”)**

Applicant: Name

Address, Zip code, Headquarters, ID number

Name of workplace1, Address, Zip code, Headquarters

Name of workplace2, Address, Zip code, Headquarters

Certificate number\*) on accreditation: \*) *to be indicated only in the case of a request for re-accreditation or extension of accreditation*

|  |  |  |  |
| --- | --- | --- | --- |
| **Article of standard/**  ***Regulation*** | | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **5** | | **General requirements** |
| **5.1** | | **Legal entity** |  |
| **5.2** | | **Responsibility for validation/verification statements** |  |
| **5.3**  ***Art. 43*** | | **Management of impartiality** |  |
| **5.4** | | **Liability** |  |
|  |
| **Article of standard/**  ***Regulation*** | | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **6** | | **Structural requirements** |
| **6.1** | | **Organizational structure and top management** |  |
| **6.2**  ***Art. 43 (2)*** | | **Operational control** |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **Article of standard/**  ***Regulation*** | | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **7** | | **Resource requirements** |
| **7.1** | | **General** |  |
| **7.2**  ***Art. 36-40, 43*** | | **Personnel** |  |
| **7.3**  ***Art. 36*** | | **Management process for the competence of personnel** |  |
| **7.4**  ***Art. 43 (5)*** | | **Outsourcing** |  |
|  |
| **Article of standard/**  ***Regulation*** | | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **8** | | **Validation/verification programme** |  |
|  | |  |  |
| **Article of standard/**  ***Regulation*** | | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **9** | | **Process requirements** |
| **9.1**  ***Chap. II AVR*** | | **General** |  |
| **9.2**  ***Chap. II AVR*** | | **Pre-engagement** |  |
| **9.3**  ***Chap. II AVR*** | | **Engagement** |  |
| **9.4**  ***Chap. II AVR*** | | **Planning** |  |
| **9.5**  ***Chap. II AVR*** | | **Validation/verification execution** |  |
| **9.6**  ***Chap. II AVR*** | | **Review** |  |
| **9.7**  ***Chap. II AVR*** | | **Decision and issue of the validation/verification statement** |  |

|  |  |  |
| --- | --- | --- |
| **Article of standard/**  ***Regulation*** | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **9.8**  ***Art. 70 MRR*** | **Facts discovered after the issue of the validation/verification statement** |  |
| **9.9** | **Handling of appeals** |  |
| **9.10** | **Handling of complaints** |  |
| **9.11**  ***Art. 26*** | **Records** |  |

|  |  |  |
| --- | --- | --- |
| **Article of standard/**  ***Regulation*** | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **10** | **Information requirements** |
| **10.1**  ***Art. 42 (2)*** | **Publicly available information** |  |
| **10.2**  ***Art. 42 (2)*** | **Other information to be available** |  |
| **10.3** | **Reference to validation/verification and use of marks** |  |
| **10.4**  ***Art. 42 (3)*** | **Confidentiality** |  |
|  |  |  |

|  |  |  |
| --- | --- | --- |
| **Article of standard/**  ***Regulation*** | **Article title** | **Description of compliance with requirement - references to relevant document articles \*)** |
| **11** | **Management system requirements** |
| **11.1**  ***Art. 41, Annex II AVR*** | **General** |  |
| **11.2**  ***Art. 41, Annex II AVR*** | **Management review** |  |
| **11.3**  ***Art. 41, Annex II AVR*** | **Internal audits** |  |
| **11.4**  ***Art. 41, Annex II AVR*** | **Corrective action** |  |
| **11.5**  ***Art. 41, Annex II AVR*** | **Actions to address risks and opportunities** |  |
| **11.6**  ***Art. 41, Annex II AVR*** | **Documented information** |  |

**\*) Insert all documents referred to in the AIS.**

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