Application of WELMEC 7.3(2019) and WELMEC 7.4(2019) guides regarding legally relevant software conformity with software requirements under Directive 2014/32/EU (MID)

This information sheet is intended for manufacturers with measuring instruments certified and/or to certify by ITE and it describes the reference documentation used by the Notified Body no. 1964, hereinafter referred as ITE, for the application of WELMEC guide 7.3(2019) and WELMEC guide 7.4(2019) regarding the conformity of the legally relevant software with the software requirements established under Directive 2014/32 / EU (MID) for module B.

References

- Reference documentation for new certifications and changes in existing certifications in relation to modules B requested to ITE from June 30th 2020.
  - WELMEC 7.2 Guide (2019) Software Guide (Directive 2014/32/EU on Measuring Instruments)
  - WELMEC 7.3 Guide (2019) Reference Architectures. Based on WELMEC Guide 7.2
  - WELMEC 7.4 Guide (2019) Exemplary Applications of WELMEC Guide 7.2

Main changes introduced

Adaptation of software certification questionnaire (PEC-ITE-B A08) to include:

- The risk analysis must include the common attack vectors provided in section 5 of WELMEC 7.3 guide, in relation to both the physical measuring instrument itself and legally relevant software running on it.
- Technical documentation must specify the modular architecture applied to instrument design.