[F1SCHEDULE 1B

CONFORMITY ASSESSMENT PROCEDURES (Annex II to the Directive)

Textual Amendments

F1 Schs. 1A-1K inserted (E.W.S.) (31.12.2020) by The Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696), reg. 1, **Sch. 27 para. 49** (with Sch. 27 para. 50(a)) (as amended by S.I. 2020/676, regs. 1(1), 2); 2020 c. 1, Sch. 5 para. 1(1)

MODULE B

TYPE EXAMINATION

1. 'Type examination' is the part of a conformity assessment procedure in which an approved body examines the technical design of an instrument and verifies and attests that the technical design of the instrument meets the requirements of these Regulations that apply to it.

2. Type examination may be carried out in either of the following manners:

(a) examination of a specimen, representative of the production envisaged, of the complete regulated measuring instrument (production type),

(b) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in paragraph 3, plus examination of specimens, representative of the production envisaged, of one or more critical parts of the instrument (combination of production type and design type);

(c) assessment of the adequacy of the technical design of the instrument through examination of the technical documentation and supporting evidence referred to in paragraph 3, without examination of a specimen (design type).

The approved body decides on the appropriate manner and the specimens required.

3. The manufacturer shall lodge an application for type examination with a single approved body of his choice.

The application shall include:

(a) the name and address of the manufacturer and, if the application is lodged by the authorised representative, his name and address as well;

(b) a written declaration that the same application has not been lodged with any other approved body;

(c) the technical documentation set out in regulations 44 and 45. The technical documentation shall make it possible to assess the instrument's conformity with the applicable requirements of these Regulations and shall include an adequate analysis and assessment of the risk(s). The technical documentation shall specify the applicable requirements and cover, as far as relevant for the assessment, the design, manufacture and operation of the instrument.

The application shall in addition contain, wherever applicable:

(d) the specimens, representative of the production envisaged. The approved body may request further specimens if needed for carrying out the test programme;

(e) the supporting evidence for the adequacy of the technical design solution. This supporting evidence shall mention any documents that have been used, in particular where the relevant

designated standards, and/or normative documents have not been applied in full. The supporting evidence shall include, where necessary, the results of tests carried out in accordance with other relevant technical specifications by the appropriate laboratory of the manufacturer, or by another testing laboratory on his behalf and under his responsibility.

4. The approved body shall:

For the instrument:

4.1. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the instrument;

For the specimen(s):

4.2. verify that the specimen(s) have been manufactured in conformity with the technical documentation and identify the elements which have been designed in accordance with the applicable provisions of the relevant designated standards and/or normative documents, as well as the elements which have been designed in accordance with other relevant technical specifications;

4.3. carry out appropriate examinations and tests, or have them carried out, to check whether, where the manufacturer has chosen to apply the solutions in the relevant designated standards and normative documents, these have been applied correctly;

4.4. carry out appropriate examinations and tests, or have them carried out, to check whether, where the solutions in the relevant designated standards, and/or normative documents have not been applied, the solutions adopted by the manufacturer applying other relevant technical specifications meet the corresponding essential requirements of these Regulations;

4.5. agree with the manufacturer on the location where the examinations and tests will be carried out.

For the other parts of the regulated measuring instrument:

4.6. examine the technical documentation and supporting evidence to assess the adequacy of the technical design of the other parts of the regulated measuring instrument.

5. The approved body shall draw up an evaluation report that records the activities undertaken in accordance with paragraph 4 and their outcomes. Without prejudice to its obligations vis-à-vis the Secretary of State, the approved body shall release the content of that report, in full or in part, only with the agreement of the manufacturer.

6. Where the type meets the requirements of these Regulations, the approved body shall issue a type examination certificate to the manufacturer. That certificate shall contain the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the necessary data for identification of the approved type. The type examination certificate may have one or more annexes attached.

The type examination certificate and its annexes shall contain all relevant information to allow the conformity of manufactured regulated measuring instruments with the examined type to be evaluated and to allow for in-service control. In particular, to allow the conformity of manufactured instruments to be evaluated with the examined type regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, content shall include:

— the metrological characteristics of the type of instrument;

— measures required for ensuring the integrity of the instruments (sealing, identification of software, etc.);

— information on other elements necessary for the identification of the instruments and to check their visual external conformity to type;

— if appropriate, any specific information necessary to verify the characteristics of manufactured instruments.

The type examination certificate shall have a validity of 10 years from the date of its issue, and may be renewed for subsequent periods of 10 years each.

Where the type does not satisfy the applicable requirements of these Regulations, the approved body shall refuse to issue a type examination certificate and shall inform the applicant accordingly, giving detailed reasons for its refusal.

7. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved type may no longer comply with the applicable requirements of these Regulations, and shall determine whether such changes require further investigation. If so, the approved body shall inform the manufacturer accordingly.

8. The manufacturer shall inform the approved body that holds the technical documentation relating to the type examination certificate of all modifications to the approved type that may affect the conformity of the instrument with the essential requirements of these Regulations or the conditions for validity of that certificate. Such modifications shall require additional approval in the form of an addition to the original type examination certificate.

9. Each approved body shall inform the Secretary of State concerning the type examination certificates and/or any additions thereto which it has issued or withdrawn, and shall, periodically or upon request, make available to the Secretary of State the list of such certificates and/or any additions thereto refused, suspended or otherwise restricted.

The other approved bodies and the Secretary of State may, on request, obtain a copy of the type examination certificates and/or additions thereto. On request, the Secretary of State may obtain a copy of the technical documentation and the results of the examinations carried out by the approved body.

The approved body shall keep a copy of the type examination certificate, its annexes and additions, as well as the technical file including the documentation submitted by the manufacturer until the expiry of the validity of that certificate.

10. The manufacturer shall keep a copy of the type examination certificate, its annexes and additions together with the technical documentation at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

11. The manufacturer's authorised representative may lodge the application referred to in paragraph 3 and fulfil the obligations set out in paragraphs 8 and 10, provided that they are specified in the mandate.**]**

Changes to legislation:
There are currently no known outstanding effects for the The Measuring Instruments Regulations 2016, MODULE B.