[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 G

CONFORMITY BASED ON UNIT VERIFICATION

1. Conformity based on unit verification is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2, 3 and 5 and ensures and declares on his sole responsibility that the instrument concerned, which has been subject to the provisions of paragraph 4, is in conformity with the requirements of these Regulations that apply to it.

Technical documentation

2. The manufacturer shall establish the technical documentation and make it available to the approved body referred to in paragraph 4. The documentation shall make it possible to assess the instrument's conformity with the relevant requirements, 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 manufacturer shall keep the technical documentation at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

Manufacturing

3. The manufacturer shall take all measures necessary so that the manufacturing process and its monitoring ensure conformity of the manufactured instrument with the applicable requirements of these Regulations.

Verification

4. An approved body chosen by the manufacturer shall carry out the appropriate examinations and tests set out in the relevant designated standards, and/or normative documents, or equivalent tests set out in other relevant technical specifications, to verify the conformity of the instrument with the applicable requirements of these Regulations, or have them carried out. In the absence of such a designated standard, or normative document, the approved body concerned shall decide on the appropriate tests to be carried out.

The approved body shall issue a certificate of conformity in respect of the examinations and tests carried out and affix its identification number to the approved instrument, or have it affixed under its responsibility.

The manufacturer shall keep the certificates of conformity at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market.

Conformity marking and declaration of conformity

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5.1. The manufacturer shall affix the UK marking and the M marking set out in these Regulations and, under the responsibility of the approved body referred to in paragraph 4, the latter's identification number to each instrument that satisfies the applicable requirements of these Regulations.

5.2. The manufacturer shall draw up a written declaration of conformity and keep it at the disposal of the market surveillance authorities for 10 years after the instrument has been placed on the market. The declaration of conformity shall identify the instrument for which it has been drawn up.

A copy of the declaration of conformity shall be made available to the market surveillance authorities upon request.

A copy of the declaration of conformity shall be supplied with the regulated measuring instrument.

Authorised representative

6. The manufacturer's obligations set out in paragraphs 2 and 5 may be fulfilled by his authorised representative, on his behalf and under his responsibility, 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 G.