[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 H1:

CONFORMITY BASED ON FULL QUALITY ASSURANCE PLUS DESIGN EXAMINATION

1. Conformity based on full quality assurance plus design examination is the conformity assessment procedure whereby the manufacturer fulfils the obligations laid down in paragraphs 2 and 6, and ensures and declares on his sole responsibility that the regulated measuring instruments concerned satisfy the requirements of these Regulations that apply to them.

Manufacturing

2. The manufacturer shall operate an approved quality system for design, manufacture and final product inspection and testing of the regulated measuring instruments concerned as specified in paragraph 3, and shall be subject to surveillance as specified in paragraph 5.

The adequacy of the technical design of the regulated measuring instruments shall have been examined in accordance with paragraph 4.

Quality system

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3.1. The manufacturer shall lodge an application for assessment of the quality system with the approved body of his choice for the regulated measuring instruments concerned.

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) all relevant information for the instrument category envisaged;

(c) the documentation concerning the quality system;

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

3.2. The quality system shall ensure compliance of the regulated measuring instruments with the requirements of these Regulations that apply to them.

All the elements, requirements and provisions adopted by the manufacturer shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions. This quality system documentation shall permit a consistent interpretation of the quality programmes, plans, manuals and records.

It shall, in particular, contain an adequate description of:

(a) the quality objectives and the organisational structure, responsibilities and powers of the management with regard to design and product quality;

(b) the technical design specifications, including standards, that will be applied and, where the relevant designated standards and/or normative documents will not be applied in full, the means that will be used to ensure that the essential requirements of these Regulations that apply to the regulated measuring instruments will be met, applying other relevant technical specifications;

(c) the design control and design verification techniques, processes and systematic actions that will be used when designing the regulated measuring instruments pertaining to the instrument category covered;

(d) the corresponding manufacturing, quality control and quality assurance techniques, processes and systematic actions that will be used;

(e) the examinations and tests that will be carried out before, during and after manufacture, and the frequency with which they will be carried out;

(f) the quality records, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned;

(g) the means of monitoring the achievement of the required design and product quality and the effective operation of the quality system.

3.3. The approved body shall assess the quality system to determine whether it satisfies the requirements referred to in paragraph 3.2. It shall presume conformity with those requirements in respect of the elements of the quality system that comply with the corresponding specifications of the relevant designated standard.

In addition to experience in quality management systems, the auditing team shall have at least one member experienced as an assessor in the relevant instrument field and instrument technology concerned, and knowledge of the applicable requirements of these Regulations. The audit shall include an assessment visit to the manufacturer's premises.

The manufacturer or his authorised representative shall be notified of the decision. The notification shall contain the conclusions of the audit and the reasoned assessment decision.

3.4. The manufacturer shall undertake to fulfil the obligations arising out of the quality system as approved and to maintain it so that it remains adequate and efficient.

3.5. The manufacturer shall keep the approved body that has approved the quality system informed of any intended change to the quality system.

The approved body shall evaluate any proposed changes and decide whether the modified quality system will continue to satisfy the requirements referred to in paragraph 3.2 or whether a re-assessment is necessary.

It shall notify the manufacturer or his authorised representative of its decision. The notification shall contain the conclusions of the examination and the reasoned assessment decision.

3.6. Each approved body shall inform the Secretary of State of quality system approvals issued or withdrawn, and shall periodically or upon request, make available to the Secretary of State the list of quality system approvals refused, suspended or otherwise restricted.

Design examination

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4.1. The manufacturer shall lodge an application for examination of the design with the approved body referred to in paragraph 3.1.

4.2. The application shall make it possible to understand the design, manufacture and operation of the instrument, and to assess the conformity with the requirements of these Regulations that apply to it.

It shall include:

(a) the name and address of the manufacturer;

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

(c) the technical documentation. 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). It shall, as far as relevant for such assessment, cover the design and operation of the instrument;

(d) the supporting evidence for the adequacy of the technical design. 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, and 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.

4.3. The approved body shall examine the application, and where the design meets the requirements of these Regulations that apply to the instrument it shall issue a design examination certificate to the manufacturer. That certificate shall give the name and address of the manufacturer, the conclusions of the examination, the conditions (if any) for its validity and the data necessary for identification of the approved design. That certificate may have one or more annexes attached.

That certificate and its annexes shall contain all relevant information to allow the conformity of manufactured regulated measuring instruments with the examined design to be evaluated and to allow for in-service control. It shall allow the evaluation of conformity of the manufactured instruments with the examined design regarding the reproducibility of their metrological performances, when they are properly adjusted using appropriate means, including:

(a) the metrological characteristics of the design of the instrument;

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

(c) information on other elements necessary for the identification of the instrument and to check its visual external conformity to the design;

(d) if appropriate, any specific information necessary to verify the characteristics of manufactured instruments;

(e) in the case of a sub-assembly, all necessary information to ensure the compatibility with other sub-assemblies or regulated measuring instruments.

The approved body shall establish an evaluation report in this regard and keep it at the disposal of the Secretary of State. Without prejudice to paragraph 9 of Schedule 5, the approved body shall release the content of this report, in full or in part, only with the agreement of the manufacturer.

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

4.4. The approved body shall keep itself apprised of any changes in the generally acknowledged state of the art which indicate that the approved design 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.

The manufacturer shall keep the approved body that has issued the design examination certificate informed of any modification to the approved design that may affect the conformity with the essential requirements of these Regulations or the conditions for validity of the certificate. Such modifications shall require additional approval – from the approved body that issued the design examination certificate – in the form of an addition to the original design examination certificate.

4.5. Each approved body shall inform the Secretary of State of the design 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 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 design examination certificates and/or additions thereto. On request, the Secretary of State may obtain a copy of the technical documentation and of the results of the examinations carried out by the approved body.

The approved body shall keep a copy of the design 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 the certificate.

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

Surveillance under the responsibility of the approved body

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5.1. The purpose of surveillance is to make sure that the manufacturer duly fulfils the obligations arising out of the approved quality system.

5.2. The manufacturer shall, for assessment purposes, allow the approved body access to the design, manufacture, inspection, testing and storage sites, and shall provide it with all necessary information, in particular:

(a) the quality system documentation;

(b) the quality records as provided for by the design part of the quality system, such as results of analyses, calculations, tests, etc.;

(c) the quality records as provided for by the manufacturing part of the quality system, such as inspection reports and test data, calibration data, qualification reports on the personnel concerned, etc.

5.3. The approved body shall carry out periodic audits to make sure that the manufacturer maintains and applies the quality system and shall provide the manufacturer with an audit report.

5.4. In addition, the approved body may pay unexpected visits to the manufacturer. During such visits the approved body may, if necessary, carry out instrument tests, or have them carried out, in order to check the proper functioning of the quality system. It shall provide the manufacturer with a visit report and, if tests have been carried out, with a test report.

Conformity marking and declaration of conformity

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6.1. 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 3.1, the latter's identification number to each individual instrument that satisfies the applicable requirements of these Regulations.

6.2. The manufacturer shall draw up a written declaration of conformity for each instrument model 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 model for which it has been drawn up and shall mention the number of the design examination certificate.

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 each regulated measuring instrument that is placed on the market. However, this requirement may be interpreted as applying to a batch or consignment rather than individual instruments in those cases where a large number of instruments is delivered to a single user.

7. The manufacturer shall, for a period ending 10 years after the instrument has been placed on the market, keep at the disposal of the market surveillance authorities:

(a) the documentation concerning the quality system referred to in paragraph 3.1,

(b) the information relating to the change referred to in paragraph 3.5, as approved;

(c) the decisions and reports of the approved body referred to in paragraphs 3.5, 5.3 and 5.4.

Authorised representative

8. The manufacturer's authorised representative may lodge the application referred to in paragraphs 4.1 and 4.2 and fulfil the obligations set out in paragraphs 3.1, 3.5, 4.4, 4.6, 6 and 7, 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 H1:.