[F1SCHEDULE 2A

Modification of Annexes to Directives 90/385, 93/42, 98/79

Textual Amendments

F1 Sch. 2A inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **12** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, 56, **57**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 1

Modification of Annexes to Directive 90/385

1.—(1) The Annexes to Directive 90/385 are modified so that they read as if amended by paragraphs 2 to 10.

(2) In this Part any reference to "the Regulations" is a reference to the Medical Devices Regulations 2002.

2. In Annex 1—

(a) in Section 8 for the fifth indent substitute —

"–risks connected with ionising radiation from radioactive substances included in the device,";

(b) for Section 10 substitute—

"**10.** Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in regulation 2 of the Human Medicines Regulations 2012, and which is liable to act upon the body with an action ancillary to that of the device, the quality, safety and usefulness of the substance must be verified by analogy with the methods specified in Annex I to Directive 2001/83/EC as modified by Schedule 8B to the Human Medicines Regulations 2012.

For the substances referred to in the first paragraph, the approved body shall, having verified the usefulness of the substance as part of the medical device and taking account of the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the substance into the device. When issuing an opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where a device incorporates, as an integral part, a human blood derivative, the approved body shall, having verified the usefulness of the substance as part of the device and taking into account the intended purpose of the device, seek a scientific opinion from the Secretary of State on the quality and safety of the substance including the clinical benefit/risk profile of the incorporation of the human blood derivative into the device. When issuing the opinion, the Secretary of State shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the approved body.

Where changes are made to an ancillary substance incorporated in a device, in particular related to its manufacturing process, the approved body shall be informed of the changes

and shall consult the Secretary of State, in order to confirm that the quality and safety of the ancillary substance are maintained. The Secretary of State shall take into account the data related to the usefulness of the incorporation of the substance into the device as determined by the approved body, in order to ensure that the changes have no negative impact on the established benefit/risk profile of the addition of the substance in the device.

When the Secretary of State has obtained information on the ancillary substance, which could have an impact on the established benefit/risk profile of the addition of the substance to the device, the Secretary of State shall provide the approved body with advice on whether this information has an impact on the established benefit/risk profile of the addition of the substance to the device or not. The approved body shall take the updated scientific opinion into account in reconsidering its assessment of the conformity assessment procedure.";

(c) in Section 14.2 —

(i) for "the name and address of the authorised representative" substitute ", where such a person is appointed under regulation 21A of the Regulations, the name and address of the UK responsible person,";

(ii) for "the Community" substitute "the United Kingdom";

(d) in Section 15 in the first indent for "CE mark" substitute "UK mark".

3. In Annex 2—

(a) for the heading substitute "Declaration of conformity";

(b) for "the notified body" each time it occurs substitute "the approved body";

(c) for "this Directive" each time it occurs substitute "the Regulations";

(d) in Section 1, for "EC Surveillance" substitute "Surveillance";

(e) in Section 2—

(i) for "his authorized representative" substitute "their UK responsible person";

(ii) omit "established within the Community";

(iii) for "CE marking" substitute "UK marking";

(f) in Section 3.1—

(i) in the opening words, for "a notified body" substitute "an approved body";

(ii) in the fifth indent, for "competent authorities" substitute "Secretary of State";

(g) in Section 3.2(c), for "Article 5" substitute "regulation 3A of the Regulations";

(h) in Section 3.3 for the first sentence substitute—

"The quality system shall be audited by an approved body to determine whether it meets the requirements referred to in Section 3.2.";

(i) in Section 3.4, in the second paragraph, for the first sentence substitute—

"The proposed modifications shall be evaluated by the approved body so as to verify whether the quality system so modified would still meet the requirements referred to in Section 3.2.";

(j) in Section 4.2 in the second indent for "Article 5" substitute "regulation 3A of the Regulations";

(k) for Section 4.3 substitute—

"**4.3.** The approved body must examine the application and, where the product complies with the relevant provisions of the Regulations, shall issue the applicant with a design certificate. The approved body may require the application to be supplemented

by further tests or proof so that compliance with the requirements of the Regulations may be evaluated. The certificate shall contain conclusions of the examination, the conditions of its validity, the data needed for identification of the approved design and, where appropriate, a description of the intended use of the product.

In the case of devices referred to in Annex 1, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(l) in Section 4.4, for each reference to "EC design" substitute "design";

(m) in Section 6.1—

(i) for "national authorities" substitute "Secretary of State";

(ii) for "his authorised representative" substitute "their UK responsible person";

(n) for Section 6.2 substitute—

"**6.2.** On request, an approved body must make available to other approved bodies and to the Secretary of State all relevant information on approvals of quality systems, issued, refused or withdrawn.";

(o) for Section 7 substitute—

"**7.** Application to the devices incorporating a human blood derivative:

Upon completing the manufacture of each batch of devices incorporating a human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

4. In Annex 3—

(a) in the title for "EC TYPE-EXAMINATION" substitute "TYPE-EXAMINATION";

(b) for "EC type-examination" in each other place substitute "type-examination";

(c) for "a notified body" in each place substitute "an approved body";

(d) for "the notified body" in each place substitute "the approved body";

(e) in Section 1, for "this Directive" substitute "the Regulations";

(f) in Section 2—

(i) for the first sentence substitute—

"The application for type-examination shall be made by the manufacturer to the approved body.";

(ii) for "the authorized representative" substitute "the UK responsible person";

(iii) for "this Directive" substitute "the Regulations";

(g) in Section 3, for each reference to "Article 5" substitute "regulation 3A of the Regulations";

(h) for Sections 4 and 5, substitute—

"**4.** The approved body shall—

4.1. examine and evaluate the documentation, verify that the type has been manufactured in accordance with that documentation; it shall also record the items which have been designed in accordance with the applicable provisions of the standards referred to in regulation 3A of the Regulations, as well as the items for which the design is not based on the relevant provisions of the said standards.

4.2. carry out or have carried out the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements where the standards referred to in regulation 3A of the Regulations have not been applied.

4.3. carry out or have carried out the appropriate inspections and the tests necessary to verify whether, where the manufacturer has chosen to apply the relevant standards, these have actually been applied.

4.4. agree with the applicant on the place where the necessary inspections and tests will be carried out.

5. Where the type meets the provisions of the Regulations, the approved body shall issue a type-examination certificate to the applicant. The certificate shall contain the name and address of the manufacturer, the conclusions of the control, the conditions under which the certificate is valid and the information necessary for identification of the type approved. The relevant parts of the documentation must be annexed to the certificate and a copy kept by the approved body.

In the case of devices referred to in Annex I, Section 10, second paragraph, the approved body shall, as regards the aspects referred to in that Section, consult the Secretary of State before taking the decision. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The scientific opinion of the Secretary of State must be included in the documentation concerning the device. The approved body will give due consideration to the views expressed in this consultation when making its decision. It must convey its final decision to the Secretary of State.

In the case of devices referred to in Annex I, Section 10, third paragraph, the scientific opinion of the Secretary of State must be included in the documentation concerning the device. The opinion of the Secretary of State shall be drawn up within 210 days after receipt of valid documentation. The approved body will give due consideration to the opinion of the Secretary of State when making its decision. The approved body may not deliver the certificate if the Secretary of State's decision is unfavorable. It must convey its final decision to the Secretary of State.";

(i) in Section 6 omit "EC" each time it occurs;

(j) for Section 7 substitute—

"**7.1.** On request, an approved body shall make available to other conformity assessment bodies (including other approved bodies) and to the Secretary of State all relevant information on type-examination certificates and addenda to those certificates issued, refused and withdrawn.

7.2. The approved body must cooperate with other approved bodies with regard to making available copies of the type examination certificates or addenda to those

certificates but, as regards copies of annexes to the certificates, must only make those available to other approved bodies with the consent of the manufacturer.

7.3. The manufacturer or their UK responsible person shall keep with the technical documentation a copy of the UK type-examination certificates and the supplements to them for a period of at least 15 years from the manufacture of the last product.".

5. For Annex 4 substitute—

"ANNEX 4

VERIFICATION

1. Verification is the procedure whereby the manufacturer ensures and declares that the products subject to the provisions of Section 3 are in conformity with the type as described in the type-examination certification and satisfy the requirements of the Regulations that apply to them.

2. The manufacturer shall take all measures necessary in order that the manufacturing process ensures conformity of the products to the type as described in the type-examination certification and to the requirements of the Regulations that apply to them. The manufacturer shall affix the UK marking to each product and draw up a written declaration of conformity.

3. The manufacturer shall, before the start of manufacture, prepare documents defining the manufacturing processes, in particular as regards sterilization, together with all the routine, pre-established provisions to be implemented to ensure uniformity of production and conformity of the products with the type as described in the type examination certificate as well as with the relevant requirements of the Regulations.

4. The manufacturer must undertake to institute and keep updated a post-marketing surveillance system including the provisions referred to in Annex 7. This undertaking must include the obligation on the part of the manufacturer to notify the Secretary of State of the following events immediately on learning of them—

(i) any change in the characteristics or performances and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or deterioration in the patient's state of health;

(ii) any technical or medical reason resulting in the withdrawal of a device from the market by a manufacturer.

5. The approved body must carry out the appropriate examinations and tests in order to check the conformity of the product to the requirements of the Regulations by examination and testing of products on a statistical basis, as specified in Section 6. The manufacturer must authorize the approved body to evaluate the efficiency of the measures taken pursuant to Section 3, by audit where appropriate.

6. Statistical verification

6.1. Manufacturers must present the products manufactured in the form of uniform batches and shall take all necessary measures in order that the manufacturing process ensures the uniformity of each batch produced.

6.2. A random sample must be taken from each batch. Products in a sample shall be individually examined and appropriate tests, as set out in the standards referred to in regulation 3A of the Regulations, or equivalent tests must be carried out to verify their conformity to the type as described in the type-examination certificate and thereby determine whether a batch is to be accepted or rejected.

6.3. Statistical control of products will be based on attributes and/or variables, entailing sampling schemes with operational characteristics which ensure a high level of safety and performance according to the state of the art. The sampling schemes will be established by the designated standards referred to in regulation 3A of the Regulations, taking account of the specific nature of the product categories in question.

6.4. Where batches are accepted, the approved body shall affix, or cause to be affixed, its identification number to each product and draw up a written certificate of conformity relating to the tests carried out. All products in the batch may be placed on the market except for those products from the sample which were found not to be in conformity. Where a batch is rejected, the approved body shall take appropriate measures to prevent the placing on the market of that batch. In the event of frequent rejection of batches the approved body may suspend the statistical verification.

The manufacturer may, with the agreement of the approved body, affix the approved body's identification number during the manufacturing process.

6.5. The manufacturer or their UK responsible person must ensure that they are able to supply the approved body's certificates of conformity on request.

7. Application to the devices incorporating human blood derivative:

Upon completing the manufacture of each batch of devices incorporating human blood derivative the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

6. For Annex 5, substitute—

"ANNEX 5

DECLARATION OF CONFORMITY TO TYPE

(Assurance of production quality)

1. The manufacturer shall apply the quality system approved for the manufacture and must conduct the final inspection of the products concerned as specified in Section 3; the manufacturer shall be subject to the surveillance referred to in Section 4.

2. This declaration of conformity is the procedural element whereby the manufacturer who satisfies the obligations of Section 1 guarantees and declares that the products concerned conform to the type described in the type-examination certificate and meet the provisions of the Regulations which apply to them.

The manufacturer must affix the UK marking in accordance with regulation 24 of the Regulations and draw up a written declaration of conformity. This declaration shall cover one or more devices manufactured, clearly identified by means of product name, product code or other unambiguous reference and must be kept by the manufacturer. The UK marking shall be accompanied by the identification number of the approved body responsible.

3. Quality system

3.1. The manufacturer shall make an application for evaluation of their quality system to an approved body.

The application shall include:

— all appropriate information concerning the products which it is intended to manufacture,

— the quality-system documentation,

— an undertaking to fulfil the obligations arising from the quality system as approved,

— an undertaking to maintain the approved quality system in such a way that it remains adequate and efficacious,

— where appropriate, the technical documentation relating to the approved type and a copy of the type-examination certificate,

— an undertaking by the manufacturer to institute and keep up-dated a post-marketing surveillance system including the provisions referred to in Annex 7. The undertaking shall include an obligation for the manufacturer to notify the Secretary of State of the following incidents immediately on learning of them:

(i) any deterioration in the characteristics or performances, and any inaccuracies in the instruction leaflet for a device which might lead to or have led to the death of a patient or a deterioration in the patient's state of health;

(ii) any technical or medical reason resulting in withdrawal of a device from the market by the manufacturer.

3.2. Application of the quality system must ensure that the products conform to the type described in the type-examination certificate.

All the elements, requirements and provisions adopted by the manufacturer for their quality system shall be documented in a systematic and orderly manner in the form of written policies and procedures. This quality-system documentation must make possible a uniform interpretation of the quality policies and procedures such as quality programmes, quality plans, quality manuals and quality records. It shall include in particular an adequate description of—

(a) the manufacturer's quality objectives;

(b) the organization of the business and in particular—

— the organizational structures, the responsibilities of the managerial staff and their organizational authority where manufacture of the products is concerned,

— methods of monitoring the efficient operation of the quality system and in particular its ability to achieve the desired quality of the products, including control of products which do not conform,

— where the manufacture and/or final inspection and testing of the products, or elements thereof, are carried out by a third party, the methods of monitoring the efficient operation of the quality system and in particular the type and extent of control applied to the third party;

(c) the techniques of control and of quality assurance at the manufacturing stage and in particular—

— the processes and procedures which will be used, particularly as regards sterilization, purchasing and the relevant documents,

— product identification procedures drawn up and kept up-to-date from drawings, specifications or other relevant documents at every stage of manufacture;

(d) the appropriate tests and trials which will be effected before, during and after production, the frequency with which they will take place, and the test equipment used.

3.3. Without prejudice to regulation 50 of the Regulations, the approved body shall effect an audit of the quality system to determine whether it meets the requirements referred to in Section 3.2. It shall presume conformity with these requirements for the quality systems which use the corresponding harmonized standards.

The team entrusted with the evaluation shall include at least one member who has already had experience of evaluations of the technology concerned. The evaluation procedure shall include an inspection on the manufacturer's premises.

The decision shall be notified to the manufacturer after the final inspection. It shall contain the conclusions of the control and a reasoned evaluation.

3.4. The manufacturer shall inform the approved body which has approved the quality system of any plan to alter that system.

The approved body shall evaluate the proposed modifications and shall verify whether the quality system so modified would meet the requirements referred to in Section 3.2; it shall notify the manufacturer of its decision. This decision shall contain the conclusions of the control and a reasoned evaluation.

4. Surveillance

4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations which arise from the approved quality system.

4.2. The manufacturer shall authorize the approved body to carry out all necessary inspections and shall supply it with all appropriate information, in particular—

— the quality-system documentation,

— the technical documentation,

— the data stipulated in the part of the quality system relating to manufacture, such as reports concerning inspections, tests, standardizations/ calibrations and the qualifications of the staff concerned, etc.

4.3. The approved body must periodically carry out appropriate inspections and evaluations in order to ascertain that the manufacturer is applying the approved quality system, and shall supply the manufacturer with an evaluation report.

4.4. In addition, the approved body may make unannounced visits to the manufacturer, and must supply the manufacturer with an inspection report.

5. The approved body shall communicate to the other approved bodies all relevant information concerning approvals of quality systems issued, refused or withdrawn.

6. Application to the devices incorporating human blood derivative:

Upon completing the manufacture of each batch of devices, incorporating human blood derivative, the manufacturer shall inform the approved body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

7. In Annex 6—

(a) in Section 1, for "authorised representative established within the Community" substitute "UK responsible person";

(b) in Section 3 for "the competent national authorities" substitute "the Secretary of State";

(c) in Section 3.1 for "this Directive" substitute "the Regulations";

(d) in Section 3.2 for the fourth indent substitute—

"–the results of the risk analysis and a list of the designated standards provided for in regulation 3A of the Regulations, applied in full or in part, and a description of the solutions adopted to satisfy the essential requirements where the standards in regulation 3A of the Regulations have not been applied,";

(e) in Section 5, in the opening paragraph, for "competent authorities" substitute "Secretary of State".

8. In Annex 7, in Section 2.3.5, for "all competent authorities of the Member States in which the clinical investigation is being performed" substitute "the Secretary of State".

9. In Annex 8—

(a) in the title for "when designating inspection bodies to be notified" substitute "when designating approved bodies";

(b) in Section 3 omit the words "and for which it has been notified";

(c) in Section 6 omit from "unless liability" to the end;

(d) in Section 7 omit from "(except *vis-à-vis"* to the end.

10. Omit Annex 9.**]**

Status:
Point in time view as at 31/12/2020.

Changes to legislation:
The Medical Devices Regulations 2002, PART 1 is up to date with all changes known to be in force on or before 11 June 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.