[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 2

Modification of Annexes to Directive 93/42

11.—(1) The Annexes to Directive 93/42 are modified so that they read as if amended by paragraphs 12 to 23.

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

12. In Annex I—

(a) in Section 3, for "Article 1(2)(a)" substitute "regulation 2(1) of the Regulations";

(b) in Section 7, for "notified body" each time it occurs substitute "approved body";

(c) for Section 7.4, substitute—

"**7.4.** 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 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 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 medical 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 must be informed of the changes and must consult the Secretary of State in order to confirm that the quality and safety of the

ancillary substance are maintained. The Secretary of State must take account of the data related to the usefulness of 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 medical device.

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

(d) in Section 7.5—

(i) for the reference to "Annex 1 to Council Directive 67/548/EEC of 27 June 1967", substitute "Regulation (EC) No. 1272/2008";

(ii) for the reference to "Annex 1 to Council Directive 67/548/EEC", substitute "the UK mandatory classification and labelling list established and maintained in accordance with Article 38A of Regulation 1272/2008";

(e) in Section 10.3 for "the provisions of Council Directive 80/181/EEC" substitute "the Units of Measurement Regulations 1986";

(f) in Section 13.3—

(i) in point (a) —

(aa) for the first two references to "the Community" substitute "Great Britain";

(bb) for the third reference to "the Community" substitute "the United Kingdom";

(cc) for "the authorised representative" substitute "the UK responsible person (where appointed in accordance with regulation 7A of the Regulations)";

(ii) in point (f) omit the second sentence;

(iii) in point (n) omit "in the case of a device within the meaning of Article 1(4a),".

13. In Annex II—

(a) in the title omit "EC";

(b) for each reference to "the notified body" substitute "the approved body";

(c) in Section 1 omit "Community";

(d) in Section 2—

(i) omit "EC";

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

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

(iv) omit the words "in accordance with Article 17";

(e) in Section 3.2—

(i) in the first paragraph for "this Directive" substitute "the Regulations"

(ii) in point (c)—

(aa) for "Article 5" substitute "regulation 3A of the Regulations";

(bb) for "Commission Directive 2003/32/EC" substitute "Commission Regulation 722/2012";

(f) for Section 3.3 substitute—

"**3.3.** The approved body must audit the quality system to determine whether it meets the requirements referred to in Section 3.2. It must presume that quality systems which implement the relevant designated standards conform to these requirements.

The assessment team must include at least one member with past experience of assessments of the technology concerned. The assessment procedure must include an assessment, on a representative basis, of the documentation of the design of the product concerned, an inspection on the manufacturer's premises and, in duly substantiated cases, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing processes.

The decision must be notified to the manufacturer. It must contain the conclusions of the inspection and a reasoned assessment.".

(g) for Section 3.4 substitute—

"**3.4.** The manufacturer must inform the approved body which approved the quality system of any plan for substantial changes to the quality system or the product-range covered. The approved body must assess the changes proposed and verify whether after these changes the quality system still meets the requirements referred to in Section 3.2. It must notify the manufacturer of its decision. This decision must contain the conclusions of the inspection and a reasoned assessment.";

(h) in Section 4.2, for "this Directive" substitute "the Regulations";

(i) 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, must 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 requirement of the Regulations may be evaluated. The certificate must 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 7.4, second paragraph, the approved body must, 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 must 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 7.4, 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 must 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.";

(j) in Section 4.4, omit each reference to "EC";

(k) in Section 6.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(l) in Section 7.1 for "Article 11(2) and (3)" substitute "regulation 13(2) and (3) of the Regulations";

(m) in Section 7.2 omit "for compliance with the provisions of this Directive";

(n) in Section 7.3 omit "for compliance with the provisions of this Directive";

(o) in Section 7.4 —

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

(ii) for "the competent authority" substitute "the Secretary of State";

(p) for Section 8, substitute—

"**8.** 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.".

14. In Annex III—

(a) for each reference to "EC type-examination" (including in the title), substitute "type-examination";

(b) in Section 1—

(i) for "a notified body" substitute "an approved body";

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

(c) in Section 2—

(i) in the first indent,—

(aa) for "authorized representative" substitute "UK responsible person" ;

(bb) for "the representative" substitute "the UK responsible person";

(ii) in the second indent, for the second and third sentences substitute—

"The applicant must provide samples at the request of the approved body.";

(iii) in the third indent, for "notified" substitute "approved";

(d) in Section 3—

(i) for each reference to "Article 5" substitute "regulation 3A of these Regulations";

(ii) for "Directive 2003/32/EC" substitute "Commission Regulation 722/2012";

(e) for Sections 4 and 5 substitute—

"**4.** The approved body must—

4.1. examine and assess the documentation, verify that the type has been manufactured in accordance with that documentation; it must 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 arrange for the appropriate inspections and the tests necessary to verify whether the solutions adopted by the manufacturer satisfy the essential requirements of the Regulations where the standards referred to in regulation 3A of the Regulations have not been applied; if the device is to be connected to another device or other devices in order to operate as intended, proof must be provided that it conforms to the essential

requirements when connected to any such device having the characteristics specified by the manufacturer;

4.3. carry out or arrange for 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 must issue a type-examination certificate to the applicant. The certificate must contain the name and address of the manufacturer, the conclusions of the inspection, 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 7.4, second paragraph, the approved body must, 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 must 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 must 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 7.4, 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 must 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.

In the case of devices manufactured utilizing tissues of animal origin referred to in Commission Regulation 722/2012, the approved body must follow the procedures referred to in that Regulation.";

(f) in Section 6—

(i) for each reference to "notified body" substitute "approved body";

(ii) omit each reference to "EC";

(g) for Section 7.2 substitute—

"**7.2.** An 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.".

(h) in Section 7.3 —

(i) for "authorised representative" substitute "UK responsible person";

(ii) omit "EC".

15. In Annex IV—

(a) omit "EC" (including in the title) each time it occurs;

(b) for both references to "this Directive" substitute "the Regulations";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 1 for "authorized representative" substitute "UK responsible person";

(e) in Section 2—

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

(ii) for "Article 17" substitute "regulation 10 of the Regulations";

(f) in Section 3 for "competent authorities" substitute "Secretary of State";

(g) for Sections 4 to 6 substitute—

"**4.** The approved body must carry out the appropriate examinations and tests in order to verify the conformity of the product with the requirements of the Regulations either by examining and testing every product as specified in Section 5 or by examining and testing products on a statistical basis as specified in Section 6, as the manufacturer decides.

The aforementioned checks do not apply to those aspects of the manufacturing process designed to secure sterility.

5. Verification by examination and testing of every product

5.1. Every product must be examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations must be carried out in order to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them.

5.2. The approved body must affix, or have affixed its identification number to each approved product and must draw up a written certificate of conformity relating to the tests carried out.

6. Statistical verification

6.1. The manufacturer must present the manufactured products in the form of homogeneous batches.

6.2. A random sample must be taken from each batch. The products which make up the sample are examined individually and the appropriate tests defined in the relevant standards referred to in regulation 3A of the Regulations or equivalent tests must be carried out to verify, where appropriate, the conformity of the products with the type described in the type-examination certificate and with the requirements of the Regulations which apply to them in order to determine whether to accept or reject the batch.

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. If the batch is accepted, the approved body affixes or has affixed its identification number to each product and draws up a written certificate of conformity relating to the tests carried out. All products in the batch may be put on the market except any in the sample which failed to conform.

If a batch is rejected, the approved body must take appropriate measures to prevent the batch from being placed on the market. In the event of frequent rejection of batches, the approved body may suspend the statistical verification.

The manufacturer may, on the responsibility of the approved body, affix the approved body's identification number during the manufacturing process.";

(h) in Section 7—

(i) for "authorised representative" substitute "UK responsible person";

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

(i) in Section 8, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 9—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012".

16. In Annex V—

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

(b) omit "EC" each time it occurs, including in the title;

(c) in Section 1, omit "Community";

(d) in Section 2—

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

(ii) for "CE marking in accordance with Article 17" substitute "UK marking";

(e) in the eighth indent of Section 3.1, for "competent authorities" substitute "Secretary of State";

(f) in Section 3.3, for the first sentence substitute—

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

(g) in Section 3.4, for the last two paragraphs substitute—

"The proposed changes must be evaluated by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(i) in Section 6 for each reference to "this Directive" substitute "the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State";

(k) in Section 7—

(i) for the words "referred to in Article 1(4a)" substitute "which incorporate a substance derived from human blood or human plasma";

(ii) for the words from "a State laboratory" to the end of that Section, substitute "a laboratory provided or arranged in accordance with section 57(1)(d) of the Health and Social Care Act 2012.".

17. In Annex VI—

(a) omit "EC" each time it occurs including in the title;

(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 2—

(i) for "CE marking in accordance with Article 17" substitute "UK marking";

(ii) for "CE marking must" substitute "UK marking must";

(e) in Section 3.1, for—

(i) "a notified body" substitute "an approved body";

(ii) "other notified body" substitute "other approved body";

(f) in Section 3.3, for the first sentence substitute—

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

(g) in Section 3.4, for the second paragraph substitute—

"The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.";

(h) in Section 5.1—

(i) for "authorised representative" substitute "UK responsible person";

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

(i) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations";

(j) in Section 6.3, for "competent authority" substitute "Secretary of State".

18. In Annex VII—

(a) in the title and in Section 1, omit "EC";

(b) in Section 1—

(i) for "authorised representative" substitute "UK responsible person";

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

(c) in Section 2 for—

(i) "his authorised representative" substitute "the manufacturer's UK responsible person";

(ii) "national authorities" substitute "Secretary of State";

(d) in Section 3—

(i) in the opening paragraph for "the Directive" substitute "the Regulations";

(ii) in the fourth indent—

(aa) for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(bb) for "of the Directive" substitute "in Annex I";

(e) in Section 4, for "competent authorities" substitute "Secretary of State";

(f) in Section 5, for "the intervention by the notified body" substitute "the intervention by the approved body";

(g) in Section 6, in the opening paragraph, for "Article 11(2)" substitute "regulation 13(2) of the Regulations".

19. In Annex VIII—

(a) in Section 1, for "authorized representative" substitute "UK responsible person";

(b) in Section 2.2 in the seventh indent for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(c) in Section 3, for "competent national authorities" substitute "Secretary of State";

(d) in Sections 3.1 and 3.2, for "this Directive" each time it occurs substitute "the Regulations";

(e) in Section 3.2—

(i) in the fourth indent, for "Article 5" in both places it occurs substitute "regulation 3A of the Regulations";

(ii) in the sixth indent, for "Directive 2003/32/EC" substitute "Regulation 722/2012";

(f) in Section 5, for "competent authorities" substitute "Secretary of State".

20. In Annex IX for "this Directive" each time it occurs substitute "the Regulations".

21. In Annex X—

(a) in Section 1.1 for "harmonised standards" substitute "designated standards";

(b) in Section 2.3.5 for the words from "all competent authorities of the Member States" to the end substitute "the Secretary of State".

22. In Annex X1—

(a) in the title, for "notified bodies" substitute "approved bodies";

(b) for the words "notified body" each time they occur substitute "approved body";

(c) for each reference to "the Directive" substitute "the Regulations";

(d) in Section 2, for "national authorities" substitute "the Secretary of State";

(e) in Section 3, for "this Directive" substitute "the Regulations";

(f) in Section 6, omit the words from ", unless liability" to the end of that Section;

(g) in Section 7, omit the words from "(except *vis a vis* the competent administrative authorities" to the end.

23. Omit Annex XII.**]**

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

Changes to legislation:
The Medical Devices Regulations 2002, PART 2 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.