STATUTORY INSTRUMENTS

2002 No. 618

The Medical Devices Regulations 2002

PART IV

In Vitro Diagnostic Medical Devices

Interpretation of Part IV

32.—(1) In this Part[F1]...—

"accessory" means an article intended specifically by its manufacturer to be used together with an*in vitro* diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not—

(a) itself an*in vitro* diagnostic medical device;

(b) an invasive sampling medical device; or

(c) a medical device which is directly applied to the human body for the purpose of obtaining a specimen;

"calibration and control material" means any substance, material or article intended by its manufacturer either to establish measurement relationships or to verify the performance characteristics of a relevant device in conjunction with the intended use of that device;

"common technical specification" means a technical specification for a relevant device referred to in a list in Annex II which has been adopted in accordance with the procedure set out in article 7(2) and published in the Official Journal of the **[**[F2]European Union**]**;

"device for self-testing" means an*in vitro* diagnostic medical device which is intended by its manufacturer to be able to be used by a member of the public in a home environment; and

"relevant device" shall be construed in accordance with regulation 33(1);

(2) In this Part[F1]..., a reference to a numbered article or Annex is to the article or Annex of Directive 98/79 bearing that number.

Textual Amendments

F1 Words in reg. 32(1)(2) omitted (1.9.2003) by virtue of The Medical Devices (Amendment) Regulations 2003 (S.I. 2003/1697), regs. 1(1)(a), **11**

F2 Words in Regulations substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **4** (with art. 3(3))

Scope of Part IV

33.—(1) The requirements of this Part in respect of relevant devices apply in respect of*in vitro* diagnostic medical devices and accessories to such devices, except for—

(a) products manufactured and used within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; and

(b) devices that come within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

(2) The requirements of this Part in respect of devices for performance evaluation do not apply in respect of—

(a) products manufactured and used only within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity; and

(b) devices that come within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, and

(i) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and

(ii) the manufacturer chooses to follow the set of arrangements in the other Directive.

[F3Registration etc. of persons placing in vitro diagnostic medical devices on the market

33A.—(1) No person may place a relevant device on the market in accordance with this Part unless that person—

(a) is established in Great Britain; and

(b) has complied with paragraph (2).

(2) A person who places a relevant device on the market complies with this paragraph if, before placing the relevant device on the market—

(a) where—

(i) that person is the manufacturer of that device and is based in Great Britain, the person informs the Secretary of State of the address of their registered place of business in Great Britain;

(ii) that person is the manufacturer of that device and is based outside the United Kingdom, the manufacturer appoints a sole UK responsible person, and that UK responsible person provides the Secretary of State with written evidence that they have the manufacturer's authority to act as their UK responsible person; or

(iii) that person is not the manufacturer of the device, the address of that person's registered place of business in Great Britain has been provided to the Secretary of State by the manufacturer or the UK responsible person;

(b) that person supplies the Secretary of State with—

(i) a description of the relevant device; and

(ii) the relevant information in paragraph (4); and

(c) that person pays to the Secretary of State the relevant fee in accordance with regulation 53.

(2A) The person responsible for providing information in accordance with paragraph (2) must inform the Secretary of State of any changes to that information.

(3) The UK responsible person appointed in accordance with paragraph (2)(a)(ii) must—

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

(d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant approved body of that termination.

(4) In this regulation "relevant information" means—

(a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;

(b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;

(c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(d) in relation to devices in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

(ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;

(e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(5) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(6) In this regulation a device is a "new relevant device" if—

(a) there has been no such device continuously available on the United Kingdom or EEA market during the previous three years for the relevant analyte or other parameter; or

(b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or EEA market during the previous three years.

(7) In paragraph (3)—

(a) the references to "technical documentation" are to be construed in accordance with Annexes III to VIII;

(b) the references to "declaration of conformity" are to be construed in accordance with Annexes III, IV, V and VII.**]**

Textual Amendments

F3 Reg. 33A inserted (E.W.S.) (30.4.2021) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(2)(c), **6(3)** (as amended by S.I. 2019/1385, reg. 1, **Sch. 2 para. 5** and S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **36**); 2020 c. 1, Sch. 5 para. 1(1)

Essential requirements for *in vitro* diagnostic medical devices

34.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless that device meets those essential requirements set out in Annex I which apply to it.

(2) Subject to regulation 39, no person shall supply a relevant device—

(a) if that supply is also a placing on the market or putting into service of that device; or

(b) in circumstances where that device has been placed on the market or put into service, unless that device meets those essential requirements set out in Annex I which apply to it.

Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements E+W+S

35.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English [F4]... .

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant **[**[F5]designated standard**]**.

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.

Extent Information

E1 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F4 Words in reg. 35(2) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **37**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 35(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **37**); 2020 c. 1, **Sch. 5 para. 1(1)**

Determining compliance of *in vitro* diagnostic medical devices with relevant essential requirements N.I.

35.—(1) In determining which are the relevant essential requirements for a particular relevant device, and whether or not it complies with any of the relevant essential requirements, account shall be taken of its intended purpose.

(2) In order to meet the essential requirements set out in Section 8 of Part B of Annex I, the information to be provided under that Section must be in English if the device may reach a final user in **[**F39Northern Ireland**]**, unless—

(a) the Secretary of State, to the extent that Directive 98/79 allows him to do so, has authorised the use of another Community language or more than one other Community language; or

(b) the relevant device is a device for self-testing, in which case the instructions for use and the label must include a translation into the official language of any member State of the Community in which the device reaches a final user.

(3) A relevant device shall be presumed to comply with an essential requirement if it conforms as respects that requirement to a relevant national standard.

(4) A relevant device shall be treated as complying with an essential requirement in respect of which there is an applicable common technical specification only if it is in conformity with that specification or, if for duly justified reasons the manufacturer has not complied with that specification, an equivalent or higher specification.

Extent Information

E8 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F39 Words in reg. 35(2) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 12**

[F6**UK marking]** of *in vitro* diagnostic medical devices E+W+S

36.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device bears a **[**F7UK marking**]** which—

(a) meets the requirements set out in **[**F8Annex 2 of Regulation 765/2008**]**;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant **[**F9approved body**]** or conformity assessment body identification number for that device.

(2) Subject to regulation 39, no person shall supply a relevant device unless, where practical and appropriate, that device bears a **[**F7UK marking**]** which—

(a) meets the requirements set out in **[**F8Annex 2 of Regulation 765/2008**]**;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant **[**F9approved body**]** or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless a **[**F7UK marking**]**, meeting the requirements set out in **[**F8Annex 2 of Regulation 765/2008**]**, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that **[**F7UK marking**]** is accompanied by any relevant **[**F9approved body**]** or conformity assessment body identification number for that device.

(4) Subject to regulation 39, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a **[**F7UK marking**]**, meeting the requirements set out in **[**F8Annex 2 of Regulation 765/2008**]**, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that **[**F7UK marking**]** is accompanied by any relevant **[**F9approved body**]** or conformity assessment body identification number for that device.

(5) Subject to regulation 39, no person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the **[**F7UK marking**]** or which reduces the visibility or the legibility of the **[**F7UK marking**]**.

Extent Information

E2 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F6 Words in reg. 36 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4A)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **38**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 36 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4A)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **38**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 36 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4A)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **38**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 36 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4A)(d)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **38**); 2020 c. 1, **Sch. 5 para. 1(1)**

CE marking of *in vitro* diagnostic medical devices N.I.

36.—(1) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless, where practical and appropriate, that device bears a CE marking which—

(a) meets the requirements set out in Annex X;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(2) Subject to regulation 39, no person shall supply a relevant device unless, where practical and appropriate, that device bears a CE marking which—

(a) meets the requirements set out in Annex X;

(b) is in a visible, legible and indelible form; and

(c) is accompanied by any relevant notified body or conformity assessment body identification number for that device,

if that supply is also a placing on the market or putting into service or if that supply is of a device that has been placed on the market or put into service.

(3) Subject to regulation 39, no person shall place on the market or put into service a relevant device unless a CE marking, meeting the requirements set out in Annex X, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(4) Subject to regulation 39, no person shall supply a relevant device (if that supply is also a placing on the market or putting into service, or if that supply is of a device that has been placed on the market or put into service) unless a CE marking, meeting the requirements set out in Annex X, appears on—

(a) any sales packaging for that device; and

(b) the instructions for use for that device,

and that CE marking is accompanied by any relevant notified body or conformity assessment body identification number for that device.

(5) Subject to regulation 39, no person shall affix any mark or inscription to, or provide any information comprising a mark or inscription on—

(a) a relevant device;

(b) the instructions for use for a relevant device; or

(c) any sales packaging for a relevant device,

which is likely to mislead a third party with regard to the meaning or the graphics of the CE marking or which reduces the visibility or the legibility of the CE marking.

Extent Information

E9 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F10UK(NI) indication: *in vitro* diagnostic medical devices

36A.—(1) Where the CE marking referred to in regulation 36 is affixed on the basis of an assessment or a certificate issued by a notified body established in the United Kingdom, a UK(NI) indication must be affixed in relation to the device, in accordance with this regulation.

(2) The UK(NI) indication must be affixed—

(a) visibly, legibly and indelibly; and

(b) before a relevant medical device is placed on the market in Northern Ireland.

(3) The UK(NI) indication must accompany the CE marking, wherever that is affixed in accordance with regulation 36.

[

F11(3A) The UK(NI) indication may be less than 5mm high provided that it is the same height as the CE marking that it accompanies.**]**

(4) The UK(NI) indication must be affixed by the manufacturer.

(5) Anyone who places a medical device on the market in Northern Ireland must ensure that the manufacturer has complied with their obligations under this regulation.

(6) No person shall supply a relevant device unless the manufacturer has affixed a UK(NI) indication as required by this regulation, if that supply is also a placing on the market or putting into service, or that supply is of a device that has been placed on the market or put into service.**]**

Textual Amendments

F10 Reg. 36A inserted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 13**

F11 Reg. 36A(3A) inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **37**

[F12UK marking of *in vitro* diagnostic devices that come within the scope of this Part and other legislation E+W+S

37. Where a relevant device (within the meaning of this Part) comes within the scope of this Part and other product safety or health and safety legislation ("the other legislation") a person must not affix a UK marking to the device unless the relevant requirements of the other legislation are also satisfied.**]**

Extent Information

E3 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F12 Reg. 37 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(4B)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **39**); 2020 c. 1, **Sch. 5 para. 1(1)**

CE marking of *in vitro* diagnostic medical devices that come within the scope of more than one Directive N.I.

37. Where a relevant device comes within the scope of Directive 98/79 and another Directive ("the other Directive") issued by one or more of the institutions of the Community, no person shall affix a CE marking to the device unless the relevant requirements of the other Directive are satisfied, except where—

(a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it;

(b) the manufacturer chooses to follow the set of arrangements in Directive 98/79;

(c) the marking of the device indicates that the device only satisfies the set of arrangements chosen by the manufacturer; and

(d) the particulars of Directive 98/79, as published in the Official Journal of the **[**F40European Union**]**, are given in the documents, notices or instructions accompanying the device.

Extent Information

E10 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F40 Words in Regulations substituted (22.4.2011) by The Treaty of Lisbon (Changes in Terminology) Order 2011 (S.I. 2011/1043), arts. 2, **4** (with art. 3(3))

In vitro diagnostic medical devices not ready for use

38. Subject to regulation 39, no person shall—

(a) put into service a relevant device;

(b) supply a relevant device—

(i) if that supply is also a putting into service of that device, or

(ii) in circumstances where that device has been placed on the market or put into service,

which is not ready for use.

Exemptions from regulations 34, 36 and 38 E+W+S

39.—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

(a) the device is not used on any specimen taken from the participants; and

(b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of F13... these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a

specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a **[**[F14]UK marking**]**, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

[[F15](3) Regulations 34 and 36 do not apply where the Secretary of State directs that a relevant device, or a class of relevant devices, which meets other requirements or standards or which is marked other than with a UK marking which the Secretary of State determines is equivalent to the requirements and standards imposed by regulations 34 and 36, may be placed on the market.

(4) In paragraph (3), the Secretary of State, in determining whether a standard or requirement or marking ("the other standard") is equivalent to a standard or requirement imposed by regulations 34 and 36, must be satisfied that the other standard imposes a degree of safety and quality equivalent to that imposed by those regulations.**]**

Extent Information

E4 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F13 Words in reg. 39(1)(b) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(5)(a)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 39(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(5)(b)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Reg. 39(3)(4) inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(5)(c)** (as amended by S.I. 2020/1478, regs. 1(3), Sch. 2 paras. 2, **40**); 2020 c. 1, **Sch. 5 para. 1(1)**

Exemptions from regulations 34, 36 and 38 N.I.

39.—(1) A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if—

(a) the device is not used on any specimen taken from the participants; and

(b) a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of Directive 98/79 or these Regulations.

(2) Regulations 34, 36 and 38 shall not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation.

Extent Information

E11 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Procedures for affixing a [F16UK marking] to *in vitro* diagnostic medical devices E+W+S

40.—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a [F17UK marking] only if its manufacturer or [F18their UK responsible person]—

(a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of [F19this Part] which apply to it; and

(c) ensures that the device meets the provisions of [F19this Part] which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a [F17UK marking] only if its manufacturer or [F18their UK responsible person]—

(a) fulfils the applicable obligations imposed by—

(i) Sections 1 to 6 of Annex III,

(ii) Annex IV, or

(iii) Annex V and either Annex VI or Annex VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F19this Part] which apply to it; and

(c) ensures that the device meets the provisions of [F19this Part] which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a [F17UK marking] only if its manufacturer or [F18their UK responsible person]—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV, or

(ii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F19this Part] which apply to it; and

(c) ensures that the device meets the provisions of [F19this Part] which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a [F17UK marking] only if its manufacturer or [F18their UK responsible person]—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV,

(ii) Annexes V and VI, or

(iii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of [F19this Part] which apply to it; and

(c) ensures that the device meets the provisions of [F19this Part] which apply to it.

Extent Information

E5 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F16 Words in reg. 40 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(5A)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **41**); 2020 c. 1, **Sch. 5 para. 1(1)**

F17 Words in reg. 40 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(5A)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **41**); 2020 c. 1, **Sch. 5 para. 1(1)**

F18 Words in reg. 40 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(5A)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **41**); 2020 c. 1, **Sch. 5 para. 1(1)**

F19 Words in reg. 40 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(5A)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **41**); 2020 c. 1, **Sch. 5 para. 1(1)**

Procedures for affixing a CE marking to *in vitro* diagnostic medical devices N.I.

40.—(1) A relevant device other than a device referred to in the lists in Annex II or a device for self-testing may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by Sections 1 to 5 of Annex III;

(b) declares, in accordance with the declaration of conformity procedure set out in that Annex, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(2) A relevant device which is a device for self-testing but which is not referred to in a list in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Sections 1 to 6 of Annex III,

(ii) Annex IV, or

(iii) Annex V and either Annex VI or Annex VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(3) A relevant device referred to in List A in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV, or

(ii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

(4) A relevant device referred to in List B in Annex II may bear a CE marking only if its manufacturer or his authorised representative—

(a) fulfils the applicable obligations imposed by—

(i) Annex IV,

(ii) Annexes V and VI, or

(iii) Annexes V and VII;

(b) declares, in accordance with a declaration of conformity procedure set out in those Annexes, that the device meets the provisions of Directive 98/79 which apply to it; and

(c) ensures that the device meets the provisions of Directive 98/79 which apply to it.

Extent Information

E12 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices E+W+S

41.—(1) A manufacturer of a relevant device or, where applicable, **[**F20their UK responsible person**]** who is required to follow, or follows or has followed a conformity assessment procedure set out in **[**F21this Part**]** shall observe the manufacturer's obligations set out in that procedure **[**F22that apply to the manufacturer or, as the case may be, their UK responsible person**]**.

(2) A manufacturer of a relevant device or, where applicable, **[**F20their UK responsible person**]** shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with **[**F21this Part**]** at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, **[**F20their UK responsible person**]** shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of **[**F23approved bodies**]** relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine M1.

(5) F24... The manufacturer or, where applicable, **[**F20their UK responsible person**]** shall, in respect of any relevant device which the manufacturer has placed on the market F25..., provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

Extent Information

E6 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F20 Words in reg. 41 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F21 Words in reg. 41 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 41(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in reg. 41(3)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(d)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F24 Words in reg. 41(5) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(e)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

F25 Words in reg. 41(5) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), **reg. 6(6)(e)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **42**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marginal Citations

M1 Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

Manufacturers etc. and conformity assessment procedures for *in vitro* diagnostic medical devices N.I.

41.—(1) A manufacturer of a relevant device or, where applicable, his authorised representative who is required to follow, or follows or has followed a conformity assessment procedure set out in Directive 98/79 shall observe the manufacturer's obligations set out in that procedure that apply to him.

(2) A manufacturer of a relevant device or, where applicable, his authorised representative shall, when following a conformity assessment procedure, take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device.

(3) A manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market or put into service, keep available for inspection by the Secretary of State—

(a) the declaration of conformity for that device;

(b) the technical documentation referred to in Annexes III to VIII relating to that device; and

(c) the decisions, reports and certificates of notified bodies relating to that device,

for a period ending five years after the manufacture of the last product.

(4) A person who in the course of manufacturing relevant devices or devices for performance evaluation removes, collects, or uses tissues, cells or substances of human origin shall, in the course of removing, collecting or using those tissues, cells or substances act in accordance with the principles laid down in the Convention of the Council of Europe for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine [M2].

(5) Until the European databank referred to in article 12 has been established, the manufacturer or, where applicable, his authorised representative shall, in respect of any relevant device which the manufacturer has placed on the market **[**[F41]in Northern Ireland**]**, provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

Extent Information

E13 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F41 Words in reg. 41(5) substituted (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 14**

Marginal Citations

M2 Council of Europe (ETS No. 164), Orviedo, 4.4.1997.

[F26Approved bodies] and the conformity assessment procedures for *in vitro* diagnostic medical devices E+W+S

42.—(1) **[**F27An approved body**]** which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out F28... at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, F29...; and

(c) lay down, by common accord with the manufacturer or **[**F30their UK responsible person**]**, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

(2) Where **[**F31an approved body**]** takes a decision in accordance with Annex III, IV, or V, they shall specify the period of validity of the decision, which, initially, shall be a period of not more than 5 years.

(3) Where **[**F32an approved body**]** and a manufacturer or **[**F33their UK responsible person**]** have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or **[**F33their UK responsible person**]**, extend the period of validity of the decision for further periods of up to 5 years, each such period commencing on the expiry of the previous period.

Textual Amendments

F26 Words in reg. 42 heading substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F27 Words in reg. 42(1) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(b)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F28 Words in reg. 42(1)(a) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(b)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F29 Words in reg. 42(1)(b) omitted (E.W.S.) (31.12.2020) by virtue of The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(b)(iii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F30 Words in reg. 42(1)(c) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(b)(iv)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F31 Words in reg. 42(2) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(c)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F32 Words in reg. 42(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(d)(i)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

F33 Words in reg. 42(3) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(7)(d)(ii)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **43**); 2020 c. 1, **Sch. 5 para. 1(1)**

UK notified bodies and the conformity assessment procedures for *in vitro* diagnostic medical devices N.I.

42.—(1) A UK notified body which is responsible for carrying out a conformity assessment procedure in relation to a relevant device shall, when carrying out the procedure—

(a) take account of the results of any assessment or verification operations which have been carried out in accordance with Directive 98/79 at an intermediate stage of manufacture of the device;

(b) take account of any relevant information relating to the characteristics and performance of that device, including in particular the results of any relevant tests and verification relating to that device already carried out before 7th June 2000; and

(c) lay down, by common accord with the manufacturer or his authorised representative, the time limits for completion of the assessment and verification operations referred to in Annexes III to VII.

(2) Where a UK notified body takes a decision in accordance with Annex III, IV, or V, they shall specify the period of validity of the decision, which, initially, shall be a period of not more than 5 years.

(3) Where a UK notified body and a manufacturer or his authorised representative have agreed that the manufacturer may apply to the body at a specified time for an extension of the period of validity of a decision referred to in paragraph (2), the body may, on application from and with the agreement of the manufacturer or his authorised representative, extend the period of validity of the decision for further periods of up to 5 years, each such period commencing on the expiry of the previous period.

Devices for performance evaluation E+W+S

43. No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or **[**F34their UK responsible person**]**—

(a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;

(b) ensures that—

(i) the device conforms with the documentation mentioned in the said section 2, and

(ii) the relevant requirements of **[**F35these Regulations**]** are complied with as respects that device; and

(c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, documentation allowing an understanding of the design, manufacture and performances of the device, including

the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations.

Extent Information

E7 This version of this provision extends to England and Wales and Scotland only; a separate version has been created for Northern Ireland only

Textual Amendments

F34 Words in reg. 43 substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(8)(a)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **44**); 2020 c. 1, **Sch. 5 para. 1(1)**

F35 Words in reg. 43(b)(ii) substituted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(8)(b)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **44**); 2020 c. 1, **Sch. 5 para. 1(1)**

Devices for performance evaluation N.I.

43. No person shall supply a device for performance evaluation (if that supply is also a making available of the device) unless the manufacturer or his authorised representative—

(a) has drawn up a statement containing the information required by Section 2 of Annex VIII and keeps that statement available for the Secretary of State for a minimum period of five years after the end of the performance evaluation;

(b) ensures that—

(i) the device conforms with the documentation mentioned in the said section 2, and

(ii) the relevant requirements of the Directive are complied with as respects that device; and

(c) undertakes to keep available, and keeps available, for the Secretary of State, for a minimum period of five years after the end of the performance evaluation, documentation allowing an understanding of the design, manufacture and performances of the device, including the expected performances, so as to allow assessment of conformity of the device with the requirements of these Regulations.

Extent Information

E14 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

[F36[F37]Registration of persons placing *in vitro* diagnostic medical devices on the market or for performance evaluation

44.—(1) Paragraph (2) applies—

(a) in relation to relevant devices that are Annex II devices or devices for self-testing, to—

(i) a manufacturer with a registered place of business in Northern Ireland who, under their own name, places on the market in Northern Ireland, or makes available for performance evaluation, any relevant device;

(ii) a UK responsible person;

(iii) a manufacturer's authorised representative who has a registered place of business in Northern Ireland;

(iv) a manufacturer with a registered place of business in Great Britain whose authorised representative does not have a registered place of business in Northern Ireland;

(b) in relation to relevant devices other than Annex II devices or devices for self-testing, to—

(i) a manufacturer who places a device on the Northern Ireland market, or makes such a device available for performance evaluation, and has a registered place of business in Northern Ireland;

(ii) an authorised representative with a registered place of business in Northern Ireland.

(2) For the purpose of enabling the Secretary of State to exercise the Secretary of State's functions under these Regulations, any person to whom this paragraph applies must—

(a) inform the Secretary of State of the address of their registered place of business; and

(b) supply the Secretary of State with—

(i) a description of each category of device concerned;

(ii) the relevant information in paragraph (7);

(c) in the case of a UK responsible person, supply the Secretary of State with—

(i) written evidence that they have been appointed as a UK responsible person;

(ii) details of the person who has appointed them; and

(iii) where the person placing the devices concerned on the market is neither the manufacturer nor the UK responsible person, the name and address of the registered place of business of the person placing the devices concerned on the market;

(d) in the case of an authorised representative, supply the Secretary of State with—

(i) written evidence that they have been designated as an authorised representative;

(ii) details of the person who has so designated them; and

(iii) where the person placing the devices concerned on the market, or making them available for performance evaluation, is neither the manufacturer nor the authorised representative, the name and address of the registered place of business of the person placing the devices concerned on the market, or making them available for performance evaluation;

(e) inform the Secretary of State of any changes to the information referred to in sub-paragraphs (a) to (d) as and when such changes arise.

(3) The obligation in paragraph 2(2)(e) to inform the Secretary of State of any changes in relation to the information referred to in sub-paragraphs (2)(a) to (d) continues to apply following the passing of any of the dates specified in paragraph (4) that apply in respect of a particular case.

(4) The obligations in paragraph (2) begin to apply—

(a) where a device is being placed on the market by a manufacturer with a registered place of business in Northern Ireland or by a person who has designated an authorised representative with a registered place of business in Northern Ireland, on 1st January 2021;

(b) in circumstances other than those described in sub-paragraph (a)—

(i) in the case of a relevant device that is a List A device, on 1st May 2021;

(ii) in the case of a relevant device that is a device for self-testing, on 1st September 2021; and

(iii) in the case of a relevant device that is a List B device, on 1st September 2021.

(5) A UK responsible person must—

(a) ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;

(b) keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements;

(c) in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device;

(d) where they have samples of the device or access to the device, comply with any request from the Secretary of State to provide such samples or access;

(e) where they have neither samples of the device nor access to the device, communicate to the manufacturer any request from the Secretary of State to provide such samples or access, and communicate to the Secretary of State whether the manufacturer intends to comply with that request;

(f) cooperate with the Secretary of State on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been appointed;

(h) if the manufacturer acts contrary to its obligations under these Regulations—

(i) terminate the legal relationship with the manufacturer; and

(ii) inform the Secretary of State and, if applicable, the relevant notified body of that termination.

(6) In this regulation the references to "technical documentation" and "declaration of conformity" are to be construed in accordance with Directive 98/79.

(7) In this regulation "relevant information" means—

(a) in relation to a new relevant device, a statement indicating that the device is a new relevant device;

(b) if the device consists wholly or partly of reagents, reagent products or calibration and control materials, appropriate information in terms of common technological characteristics and analytes;

(c) if the device does not wholly or partly consist of reagents, reagent products or calibration and control materials, the appropriate indications;

(d) in relation to devices in a list in Annex II and devices for self-testing—

(i) all data allowing for identification of such devices, the analytical and, where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex 1;

(ii) if requested by the Secretary of State, the labelling and instructions for use for when the device is placed on the market or put into service;

(e) in relation to devices for performance evaluation which relate either to devices referred to in a list in Annex II or to devices for self-testing, all data allowing for identification of such devices, the analytical and where appropriate, diagnostic parameters as referred to in Section 3 of Part A of Annex I.

(8) Within two years of the placing of a new relevant device on the market, the Secretary of State may, where the Secretary of State considers it justified, request a report relating to the experience gained with the device subsequent to it being placed on the market.

(9) In paragraphs (7) and (8) a device is a "new relevant device" if—

(a) there has been no such device continuously available on the United Kingdom or EEA market during the previous three years for the relevant analyte or other parameter; or

(b) use of the device has involved analytical technology not continuously used in connection with a given analyte or other parameter on the United Kingdom or EEA market during the previous three years.**]]**

Textual Amendments

F36 Reg. 44 revoked (E.W.S.) (30.4.2021) by S.I. 2002/618, **reg. 4D(8)** (as inserted by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **3(7)** (as amended by S.I. 2020/1478, regs. 1(3), **Sch. 2 para. 2**); 2020 c. 1, **Sch. 5 para. 1(1)**)

F37 Regs. 44, 44ZA substituted for reg. 44 (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 15**

[F38Obligations in Part IV which are met by complying with obligations in Directive 98/79 E+W+S

44ZA.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Directive 98/79 as amended from time to time;

(b) "Regulation 722/2012" means Commission Regulation (EU) 722/2012 as it applies in the European Union;

(c) "CE marking" means the CE marking required by Article 16 and shown in Annex X;

(d) "harmonised standard" is to be construed in accordance with Article 5.

(2) Where paragraph (3) applies regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

(i) that the device meets the essential requirements set out in Annex I and, where applicable, Regulation (EU) 722/2012, which apply to it; or

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 9;

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical and other relevant documentation required by a relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedure set out in Annexes III, IV, V, VI or VII;

(f) draws up an EU Declaration of Conformity in accordance with Article 9;

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where before a relevant device intended for performance evaluation is made available in Great Britain for the purpose of a performance evaluation, the manufacturer—

(a) has supplied the relevant written notice which must be in English in the form required by Sections 1 and 2 of Annex VIII;

(b) has provided an undertaking to the Secretary of State to keep available the documentation required by Annex VIII for the period specified in Section 3 of Annex VIII;

(c) has taken all necessary measures to ensure that the manufacturing process for the device produces devices in accordance with the documentation referred to in the first paragraph of Section 3 of Annex VIII.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".**]**

Textual Amendments

F38 Regs. 44ZA, 44ZB inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(10)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **46**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F37Requirement to appoint a UK responsible person for placing *in vitro* diagnostic medical devices on the market or for performance evaluation N.I.

44ZA.—(1) Paragraph (2) applies in relation to a manufacturer who—

(a) does not have a registered place of business in the United Kingdom;

(b) has not designated an authorised representative who has a registered place of business in Northern Ireland; and

(c) places a relevant device a device that is an Annex II device or a device for self-testing, on the market in Northern Ireland; or

(d) makes available such a device for performance evaluation.

(2) A manufacturer to whom this paragraph applies must appoint a person with a registered place of business in the United Kingdom as their UK responsible person to carry out the tasks described in regulations 44(2) and (5).**]**

Extent Information

E15 This version of this provision extends to Northern Ireland only; a separate version has been created for England and Wales and Scotland only

Textual Amendments

F37 Regs. 44, 44ZA substituted for reg. 44 (N.I.) (31.12.2020 immediately before IP completion day) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 (S.I. 2020/1478), reg. 1(3), **Sch. 1 para. 15**

[F38Obligations in Part IV of these Regulations which are met by complying with obligations in Regulation (EU) 2017/746

44ZB.—(1) In this regulation—

(a) any reference to an Article or Annex is a reference to that Article or Annex in Regulation (EU) 2017/746 as it has effect in EU law;

(b) "CE marking" means the CE marking required by Article 18 and presented in Annex V;

(c) "harmonised standard" has the meaning given in Article 2(73);

(d) "sponsor" has the meaning given in Article 2(57).

(2) Where paragraph (3) applies, regulations 34, 36(1) to (4), 37 and 40 are treated as being satisfied.

(3) This paragraph applies where, before placing a relevant device on the market, the manufacturer—

(a) ensures—

(i) that the device meets the general safety and performance requirements in Annex I which apply to it; or

(ii) that paragraphs (6) and (7) apply;

(b) ensures that the relevant conformity assessment procedure that applies to the device has been carried out in accordance with Article 48;

(c) ensures that the documentation required by the relevant conformity assessment procedure is drawn up;

(d) ensures that the technical documentation required by Annexes II and III and other relevant documentation required by the relevant conformity assessment procedure is prepared in or translated into English;

(e) affixes a CE marking and, where applicable, the identification number of the notified body which carried out the relevant conformity assessment on the device in accordance with the procedures set out in Annexes IX, X and XI;

(f) draws up an EU declaration of conformity in accordance with Article 17; and

(g) ensures that the declaration of conformity is prepared in or translated into English.

(4) Where paragraph (5) applies, regulation 43 is treated as being satisfied.

(5) This paragraph applies where, before a person supplies or makes available a device falling within Part IV for the purposes of performance evaluation, the sponsor of the performance evaluation—

(a) has been able to provide the Secretary of State with the required notice in the form of the application required by Chapter I of Annex XIV in English;

(b) has been able to provide the Secretary of State with an undertaking to keep available information contained in the application in accordance with Chapter II of Annex XIV.

(6) Where paragraph (7) applies, a relevant device referred to in that paragraph is also treated as complying with the relevant essential requirements referred to in regulation 35(3) and (4).

(7) This paragraph applies where—

(a) a relevant device conforms with a harmonised standard or part of a harmonised standard, which corresponds exactly to a designated standard or part of a designated standard; or

(b) a relevant device is in conformity with a common technical specification.

(8) For the purpose of this regulation, in regulations 36(5), 51 and 61(8), each reference to "UK marking" is to be read as a reference to "CE marking".**]**

Textual Amendments

F38 Regs. 44ZA, 44ZB inserted (E.W.S.) (31.12.2020) by The Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/791), regs. 1(1), **6(10)** (as amended by S.I. 2020/1478, reg. 1(3), Sch. 2 paras. 2, **46**); 2020 c. 1, **Sch. 5 para. 1(1)**

Status:
Point in time view as at 27/07/2021.

Changes to legislation:
The Medical Devices Regulations 2002, PART IV is up to date with all changes known to be in force on or before 19 July 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.