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.

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

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 the United Kingdom, 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.

CE marking of*in vitro* diagnostic medical devices

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.

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

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 **[**F2European Union**]**, are given in the documents, notices or instructions accompanying the device.

Textual Amendments

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))

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

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.

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

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.

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

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 [M1].

(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 in the United Kingdom, provide the Secretary of State with the data referred to in article 12(1)(a), and that data shall be provided in English.

Marginal Citations

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

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

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

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.

Registration of manufacturers etc. of*in vitro* diagnostic medical devices and devices for performance evaluation

44.—(1) Subject to paragraph (3), for the purpose of enabling the Secretary of State to exercise his functions under these Regulations, any person to whom this paragraph applies shall give the Secretary of State the following information—

(a) the address of his registered place of business in the United Kingdom;

(b) in the case of an authorised representative, sufficient evidence that he is the authorised representative of the manufacturer;

(c) in relation to a new relevant device, a statement indicating that the device is a new relevant device, and for the purposes of this regulation a device is a "new relevant device" if—

(i) there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter, or

(ii) use of the device involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years;

(d) in relation to a new relevant device, if requested by the Secretary of State (such a request only being permissible within two years from the date on which the Secretary of State was notified that the device was a new relevant device, and on justified grounds), a report relating to the experience gained with the device subsequent to its being placed on the market;

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

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

(g) in relation to devices referred to 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 I, the outcome of performance evaluation pursuant to Annex VIII, and certificates, and

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

(h) 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,

and shall notify him of any significant change to that information including discontinuation of the placing on the market of the device.

(2) Paragraph (1) applies to—

(a) a manufacturer with a registered place of business in the United Kingdom who places a relevant device on the market, or who makes available a device for performance evaluation, under his own name; and

(b) a person with a registered place of business in the United Kingdom who places a relevant device on the market in the United Kingdom, or who makes available a device for performance evaluation, on behalf of a manufacturer who does not have a registered place of business in the Community or in a State which is a Party to an Association Agreement as his authorised representative.

(3) Registration under this regulation is not required if—

(a) the device was first placed on the market in another Member State of the Community or in a State which is a Party to an Association Agreement (if that Agreement contains measures relating to the mutual recognition of the results of conformity assessment undertaken in respect of that device); and

(b) the manufacturer or his authorised representative has already registered with the competent authorities of that other State.

Status:
Point in time view as at 22/04/2011.

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 26 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.