Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 920/2013

of 24 September 2013

on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices[(1)], and in particular Article 11(2) thereof,

Having regard to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices[(2)], and in particular Article 16(2) thereof,

Whereas:

(1) Technical progress has led to more complex devices and production methods implying new conformity assessment challenges for notified bodies. Those developments have resulted in variations in the level of competence of notified bodies and in different degrees of stringency applied by them. Accordingly, to ensure the smooth functioning of the internal market, it is necessary to determine a common interpretation of the main elements of the criteria for designation of notified bodies set out in Directive 90/385/EEC and Directive 93/42/EEC.

(2) The common interpretation of the criteria for designation provided by this Regulation does not suffice to assure their consistent application. The assessment methods in the Member States differ. They have a tendency to differ ever more due to the mentioned increased complexity of the work of conformity assessment bodies. Furthermore, many ad hoc questions arise in the day-to-day designation practice, in relation with new technologies and products. For these reasons, it is necessary to provide for procedural obligations which ensure a constant dialogue between Member States on their general practices and on ad hoc questions. This will bring to the surface discrepancies in the methods used to assess the conformity assessment bodies and in the interpretation of the criteria for their designation set out in Directive 90/385/EEC and Directive 93/42/EEC. Bringing the discrepancies to the surface will permit to develop a common interpretation of the assessment methods, especially with regard to new technologies and devices.

Changes to legislation: *Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

(3) To ensure a common approach from the designating authorities and neutral conditions for competition those authorities should base their decisions on a common set of documents which lay the ground for the verification of the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(4) To facilitate, in a view of the increasingly complex work of conformity assessment bodies, a common application of the criteria established for their designation, those bodies should be assessed by teams of assessors representing the knowledge and experience of different Member States and of the Commission. To facilitate such assessments, certain essential documents should be accessible to those involved in these activities. Designating authorities from Member States other than the Member State where the conformity assessment body is established should have the possibility to review the documentation related to the assessment and to comment on intended designations if they so wish. The access to those documents is necessary in order to allow the identification of weaknesses of the applicant conformity assessment bodies as well as discrepancies in the Member States' assessment methods and in their interpretation of the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(5) In order to ensure that the common interpretation of the criteria established applies similarly to scope extensions, which often reflect new technologies or product types and renewal of designations of notified bodies, the procedure for the designation of conformity assessment bodies should also be followed in those situations.

(6) The need for control and monitoring of notified bodies by the designating authorities has increased since technical progress has raised the risk that notified bodies do not possess the necessary competence with regard to new technologies or devices emerging within their scope of designation. As technical progress shortens product cycles and as the intervals of surveillance on-site assessments and of the monitoring vary between designating authorities, minimum requirements with regard to the intervals of the surveillance and monitoring of the notified bodies should be established and unannounced or short-notice on-site assessments should be organised.

(7) When, in spite of the measures taken to ensure a coherent application and follow up of the requirements by the Member States, the competence of a notified body is in doubt, the Commission should have the possibility to investigate individual cases. The need for investigation by the Commission is exacerbated since technical progress has increased the risk that notified bodies do not possess the necessary competence with regard to new technologies or products falling under their scope of designation.

(8) In order to increase transparency and mutual trust and to further align and develop their designation, extension and renewal procedures, above all in a view of new emerging interpretative questions regarding new technologies and devices, Member States should cooperate with each other and with the Commission. They should consult each other and the Commission on questions with general relevance for the implementation of this Regulation and inform each other and the Commission on their model assessment checklist, which constitutes the basis for their assessment practice.

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(9) The increased complexity of the tasks regarding the designation of the conformity assessment bodies, reflecting the increasing complexity of the work of those bodies, requires significant resources. Therefore, requirements should be imposed on the Member States with regard to the minimum level of available competent personnel, able and entrusted to operate in an independent way.

(10) Designating authorities who are not in charge of market surveillance and vigilance for medical devices are not necessarily aware of deficiencies in the work of notified bodies which were spotted by the competent authorities when doing product checks. Furthermore, the designating authorities do not necessarily have all the product related knowledge which is sometimes needed to assess whether the notified bodies worked properly. Therefore, the designating authorities should consult the competent authorities.

(11) Where designation is based on accreditation in the meaning of Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93[(3)], in order to ensure a transparent and coherent application of the criteria set out in Annex 8 to Directive 90/385/EEC and Annex XI to Directive 93/42/EEC, accreditation bodies on the one hand, and designating and competent authorities on the other hand should exchange information relevant for the assessment of notified bodies. The need for this exchange of information has proven to be particularly strong in respect to the conformity assessment bodies' practices with regard to new technologies and devices and their ability to cover those technologies and devices and thus to fulfil the criteria for designation set out in Directive 90/385/EEC and Directive 93/42/EEC.

(12) It is appropriate to provide for a phase-in period, so as to give designating authorities time to build up the necessary additional resources and adapt their procedures.

(13) The complex technical and production developments have led some notified bodies to outsource parts of their assessments. It is therefore necessary to set the limits and to determine under which conditions this can be done. Notified bodies should be in control of their subcontractors and of their subsidiaries. They need to be endowed with the appropriate resources, including fully qualified staff to make their own assessments or to review the assessments made by external experts.

(14) To ensure that decisions by notified bodies are not influenced by non-legitimate circumstances the organisation and operation of the bodies should ensure full impartiality. To be able to carry out their tasks in a coherent and systematic manner the bodies should possess a satisfactory management system including provisions on professional secrecy. In order to allow notified bodies to perform their work properly, the level of knowledge and competence of the personnel should be guaranteed at all times.

(15) The measures provided for in this Regulation are in accordance with the opinion of the Committee set up by Article 6(2) of Directive 90/385/EEC,

HAS ADOPTED THIS REGULATION:

Changes to legislation: *Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

Modifications etc. (not altering text)

C1 Regulation applied (31.12.2020) by S.I. 2002/618, **reg. 4L(3)-(5)** (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)**)

Article 1 *U.K.*

Definitions

For the purposes of this Regulation, the following definitions shall apply:

(a) 'device' means active implantable medical devices as defined in **[**F1regulation 2(1) of the Medical Devices Regulations 2002**]**;

(b) 'conformity assessment body' means a body which performs calibration, testing, certification and inspection activities under Article R1(13) in Annex I to Decision No 768/2008/EC of the European Parliament and of the Council(4);

(c) **[**F2"approved body" has the same meaning as in regulation 2(1) of the Medical Devices Regulations 2002;**]**

(d) **[**F3"accreditation" means an attestation by a national accreditation body conveying formal recognition that a conformity assessment body is competent to carry out a specific activity;**]**

(e) F4...

(f) F5...

(g) 'on-site assessment' means a verification in the premises of the body or of one of its subcontractors or subsidiaries by the **[**F6Secretary of State**]**;

(h) 'surveillance on-site assessment' means a periodic routine on-site assessment which is neither the on-site assessment undertaken for the initial designation, nor the on-site assessment undertaken for the renewal of the designation;

(i) 'observed audit' means **[**F7the Secretary of State's**]** assessment of the performance of a notified body's audit team in the premises of the body's client;

(j) 'functions' means the tasks to be fulfilled by the body's staff and its external experts, namely: auditing of the quality systems, product related technical documentation review, review of clinical evaluations and investigations, device testing and, for each of the previously mentioned items, the final review and decision making thereon;

(k) 'subcontracting' means the transfer of tasks to one of the following:

(i) a legal person;

(ii) a natural person who further delegates these tasks or parts thereof;

(iii) several natural or legal persons who jointly perform these tasks.

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Textual Amendments

F1 Words in Art. 1(a) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 17**

F2 Art. 1(c) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 18**

F3 Art. 1(d) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 19**

F4 Art. 1(e) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 20**

F5 Art. 1(f) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 20**

F6 Words in Art. 1(g) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 21**

F7 Words in Art. 1(i) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 22**

[F8 Article 1a U.K.

In this Regulation, any reference to Annex 8 to Directive 90/385 or to Annex XI to Directive 93/42 is to be construed as a reference to those Annexes as they applied immediately before IP completion day and as modified by Schedule 2A to the Medical Devices Regulations 2002.**]**

Textual Amendments

F8 Art. 1a inserted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 23**

Article 2 U.K.

Interpretation of designation criteria

The criteria set out in Annex 8 to Directive 90/385/EEC or in Annex XI to Directive 93/42/EEC shall be applied as laid down in Annex I.

Article 3 U.K.

Procedure for the designation of [F9approved] bodies

1 When applying for designation as **[**F10an approved body**]**, a conformity assessment body shall use the application form set out in Annex II. If the conformity assessment body submits the application and documents annexed to the application on paper, it shall also submit an electronic copy of the application and its annexes.

The application shall specify the conformity assessment activities, the conformity assessment procedures and the fields of competence for which the conformity assessment body wishes to be **[**F11approved**]**, the latter by indicating the codes **[**F12found

Changes to legislation: Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes

in Guidance: UK approved bodies for medical devices https://www.gov.uk/publications/medical-devices-uk-approved-bodies-for-medical-devices.**]**

2 **[**F13The Secretary of State**]** shall assess that body in accordance with an assessment check-list that covers at least the items listed in Annex II. The assessment shall include an on-site assessment.

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7 F16...

The validity of the designation shall be limited up to a maximum of five years.

Textual Amendments

F9 Word in Art. 3 heading substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(a)**

F10 Words in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(b)**

F11 Word in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(c)(i)**

F12 Words in Art. 3(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(c)(ii)**

F13 Words in Art. 3(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(d)(i)**

F14 Words in Art. 3(2) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(d)(ii)**

F15 Art. 3(3)-(6) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(e)**

F16 Words in Art. 3(7) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 24(f)**

Article 4 U.K.

Extension and renewal of designation

1 An extension of the scope of the **[**F17approved**]** body's designation may be granted in accordance with Article 3.

2 A designation as **[**F18an approved**]** body may be renewed in accordance with Article 3 before the end of the validity period of the previous designation.

3 For the purposes of paragraph 2, the procedure set out in Article 3(2) shall include, where appropriate, an observed audit.

4 Extension and renewal procedures may be combined.

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[[F19]5 An approved body, within the meaning of regulation A45(1)(b) of the Medical Devices Regulations 2002, whose designation does not have a stated validity period or has a validity period exceeding five years, is to be subject to a renewal within five years of IP completion day**]**

[[F20]6 By way of derogation from paragraph 2, during the period from 19 May 2020 to 25 May 2021, the designating authority of a Member State, in extraordinary circumstances resulting from the COVID-19 pandemic and due to the adoption of Regulation (EU) 2020/561 of the European Parliament and of the Council[(5)] deferring the application of certain provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council[(6)], may decide to renew a designation as notified body without having recourse to the procedures laid down in Article 3.

In order to decide on the renewal of a designation as notified body in accordance with the first subparagraph, the designating authority shall carry out an assessment in order to verify the continuous competence of the notified body and its ability to perform the tasks for which it was designated.

The decision on the renewal of a designation as notified body in accordance with this paragraph shall be adopted before the end of the validity period of the preceding designation and shall automatically become void at the latest on 26 May 2021.

The designating authority shall notify the Commission of its decision, giving substantive reasons therefore, on the renewal of a designation as notified body in accordance with this paragraph by means of the 'New Approach Notified and Designated Organisations' Information System.

The Commission may require a designating authority to provide it with the results of the assessment supporting the decision on the renewal of a designation as notified body in accordance with this paragraph, as well as the outcome of related surveillance and monitoring activities, including those referred to in Article 5.**]**

Textual Amendments

F17 Word in Art. 4(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(a)**

F18 Words in Art. 4(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(b)**

F19 Art. 4(5) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 25(c)**

F20 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

Article 5 *U.K.*

Surveillance and monitoring

1 For the purpose of surveillance, the **[**[F21]Secretary of State**]** shall assess an appropriate number of **[**[F22]approved**]** body's reviews of the manufacturer's clinical evaluations and shall carry out an appropriate number of file reviews, surveillance on-site assessments and observed audits at the following intervals:

a at least every 12 months for **[**[F22]approved**]** bodies with more than 100 clients;

b at least every 18 months for all other **[**[F22]approved**]** bodies.

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That designating authority shall, in particular, examine changes which have occurred since the last assessment and the work the **[**F22approved**]** body has performed since that assessment.

[F20By way of derogation from the first and second subparagraphs, in exceptional circumstances relating to the COVID-19 pandemic that temporarily prevent the designating authority of a Member State from carrying out surveillance on-site assessments or observed audits, it shall carry out any measures to ensure an adequate level of surveillance that remain possible under those circumstances in addition to the assessment of an appropriate number of the **[**F22approved**]** body's reviews of the manufacturer's technical documentation, including clinical evaluations. **[**F23The Secretary of State**]** shall examine changes to the organisational and general requirements set out in Annex II that have occurred since the last on-site assessment and the activities the **[**F22approved**]** body has performed thereafter.**]**

2 Surveillance and monitoring conducted by the **[**F24Secretary of State**]** shall appropriately address subsidiaries.

3 **[**F25The Secretary of State shall continuously monitor that body to ensure ongoing compliance with the applicable requirements. The Secretary of State shall provide for a systematic follow-up of complaints, vigilance reports and other information, including from outside the United Kingdom, which might indicate the non-fulfilment of the obligations by an approved body or its deviation from common or best practice.**]**

In addition to surveillance or renewal on-site assessments, the **[**F26Secretary of State**]** shall initiate unannounced or short-notice on-site assessments if those on-site assessments are needed to verify compliance.

Textual Amendments

F20 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

F21 Words in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(ii)**

F22 Word in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(i)**

F23 Words in Art. 5(1) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(a)(iii)**

F24 Words in Art. 5(2) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(b)**

F25 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(c)(i)**

F26 Words in Art. 5(3) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 26(c)(ii)**

[F27*Article 6* U.K.

Investigation of the competence of an approved body

The Secretary of State may investigate cases regarding the competence of an approved body or the fulfilment of the requirements and responsibilities to which an approved body is subject under the Medical Devices Regulations 2002.**]**

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Textual Amendments

F27 Art. 6 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 27**

F28 Article 7 U.K.

Exchange of experience on designation and supervision of conformity assessment bodies

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Textual Amendments

F28 Art. 7 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 28**

F29 Article 8 U.K.

Operating of designating authorities

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Textual Amendments

F29 Art. 8 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 28**

[F30 Article 9 U.K.

Cooperation with accreditation bodies

Where designation is based on accreditation within the meaning of Regulation (EC) No 765/2008, the Secretary of State shall ensure that the accreditation body that has accredited a particular approved body is kept informed of incident reports and other information that relate to matters under the control of the approved body when the information may be relevant for the assessment of the performance of the approved body. The Secretary of State must ensure that the accreditation body in charge of the accreditation of a particular conformity assessment body is kept informed of findings relevant for the accreditation. The accreditation body shall inform the Secretary of State of its findings.**]**

Textual Amendments

F30 Art. 9 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 29**

Changes to legislation: Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes

Article 10 U.K.

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply to extension of designations as from 25 December 2013.

F31 …

Textual Amendments

F31 Words in Signature omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 30**

***Changes to legislation:** Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

ANNEX I U.K.

Interpretation of the criteria set out in Annex 8 to Directive 90/385/EEC and in Annex XI to Directive 93/42/EEC

1. Sections 1 and 5 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements: U.K.

1.1. The conformity assessment body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities. The conformity assessment body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.

1.2. That conformity assessment body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities. The conformity assessment body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement of its staff in consultancy services in the field of medical devices prior to taking up employment with the body.

1.3. That conformity assessment body, its top management and the personnel responsible for carrying out the conformity assessment tasks shall not:

(a) engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;

(b) offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide or have offered or provided, during the last three years, consultancy services to the manufacturer, his **[**F32UK responsible person**]**, a supplier or a commercial competitor as regards F33... requirements for the design, construction, marketing or maintenance of the products or processes under assessment. This does not preclude conformity assessment activities for manufacturers and economic operators mentioned above or general training activities relating to medical device regulations or related standards that are not client specific.

1.4. The conformity assessment body's top level management and its assessment personnel shall be impartial. The remuneration of the top level management and assessment personnel of a conformity assessment body shall not depend on the number or the results of assessments carried out.

1.5. F34...

1.6. The conformity assessment body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity in its conformity assessment activities.

1.7. The requirements of points 1.1 to 1.6 do not preclude exchanges of technical information and regulatory guidance between a body and a manufacturer seeking their conformity assessment.

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Textual Amendments

F32 Words in Annex 1 s. 1.3(b) substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 31(a)(i)**

F33 Word in Annex 1 s. 1.3(b) omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 31(a)(ii)**

F34 Annex 1 s. 1.5 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 31(b)**

2. The second paragraph of Section 2 of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements: U.K.

2.1. Subcontracting shall be limited to specific tasks. The subcontracting of the auditing of quality management systems or of products related reviews in its entirety is not allowed. The conformity assessment body shall in particular keep internal the review of the qualification and the monitoring of the performance of the external experts, the experts' assignment to specific conformity assessment activities, and the final review and decision-making functions.

2.2. Where a conformity assessment body subcontracts specific tasks or consults external experts related to the conformity assessment, it shall have a policy describing the conditions under which subcontracting or the consultation of external experts may take place. Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.

2.3. The conformity assessment body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.

3. Sections 3 and 4 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements: U.K.

3.1. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been or wishes to be notified, a conformity assessment body shall have within its organisation the following elements:

(a) the necessary administrative, technical, clinical and scientific personnel with technical and scientific knowledge and sufficient and appropriate experience relating to medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data;

(b) a documented process for the conduct of the conformity assessment procedures for which it is designated[7] taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.

3.2. The conformity assessment body shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.

3.3. The conformity assessment body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its

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sustainable economic viability, taking into account specific circumstances during an initial start-up phase.

3.4. The conformity assessment body shall have a quality management system in place and operating.

3.5. The experience and knowledge of the personnel responsible for carrying out conformity assessment activities shall be interpreted as including the following:

(a) sound scientific, technical and vocational training, in particular in the relevant fields of medicine, pharmacy, engineering or other relevant sciences, covering all the conformity assessment activities in relation to which the body has been notified or wishes to be notified;

(b) substantial relevant experience covering all the conformity assessment activities in relation to which the body has been notified or wishes to be notified;

(c) satisfactory knowledge of the requirements of the assessments they carry out and adequate authority to carry out those assessments;

(d) appropriate knowledge and understanding of the relevant provisions of the medical devices legislation and of the applicable harmonised standards;

(e) the ability to draw up certificates, records and reports demonstrating that assessments have been carried out.

3.6. The conformity assessment body shall establish and document qualification criteria and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing training). The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of animal origin, clinical evaluation) covered by the scope of designation.

3.7. The conformity assessment body shall have procedures in place to ensure that its subsidiaries operate on the basis of the same operating procedures and with the same stringency as its headquarters.

3.8. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel, invasive and implantable medical devices or technologies, the conformity assessment body shall have adequate internal competence in each product area for which it is designated to direct the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification. The internal competence requested shall cover technological, clinical and auditing aspects.

4. Sections 6 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements: U.K.

4.1. The conformity assessment body shall take out appropriate liability insurance corresponding to the conformity assessment activities for which it is notified, including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State under domestic legislation or the Member State itself carries out the inspections directly.

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5. Sections 7 of Annex 8 to Directive 90/385/EEC and of Annex XI to Directive 93/42/EEC shall be interpreted as including the following elements: U.K.

5.1. The conformity assessment body shall ensure that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors or any associated body, except when disclosure is required by law. To this end, it shall have documented procedures in place.

5.2. The personnel of a conformity assessment body shall observe professional secrecy with regard to all information obtained in carrying out their tasks, except in relation to the designating authorities and the competent authorities or the Commission. Proprietary rights shall be protected. To this end, the conformity assessment body shall have documented procedures in place.

ANNEX II U.K.

Application form to be submitted when applying for designation as [F35an approved] body

Textual Amendments

F35 Words in Annex 2 heading substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(a)**

Designating authority: …

Name of the applying conformity assessment body: …

Previous name (if applicable): …

[F36Approved**]** Body number (if applicable): …

Textual Amendments

F36 Word in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(b)**

Address: …

…

…

…

Contact person: …

E-mail: …

Telephone: …

Legal form of the conformity assessment body: …

***Changes to legislation:** Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

Company registration number: …

At company register: …

…

…

The following documents shall be added. In case of extension or renewal, only new or modified documents shall be submitted.

Item/issue		**Corresponding Annex I section**	**Attachment number + Reference(Section/ page)**
ORGANISATIONAL AND GENERAL REQUIREMENTS			
Legal status and organisational structure			
1	Company statutes		
2	Extract of company registration or enrolment act (Company register)		
3	Documentation on the activities of the organisation to which the conformity assessment body belongs (if any) and its relationship with the conformity assessment body		
4	Documentation on entities the conformity assessment body owns (if any) **F37** …		
5	Description of legal ownership and the legal or natural persons exercising control of the conformity assessment body		
6	Description of organisational structure and the operational management of		

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	the conformity assessment body		
7	Descriptions of functions, responsibilities and authorities of top-level management		
8	List of all staff who have an influence in the conformity assessment activities		
9	Documentation on other services provided by the conformity assessment body (if any) (e.g. consultancy relevant to devices, training etc.)		
10	Documentation on accreditation(s) relevant to this application		
Independence and impartiality			
11	Documentation on structures, policies and procedures to safeguard and promote the principles of impartiality throughout the organisation, personnel and assessment activities, including ethical rules or codes of conduct		
12	Description of how the conformity assessment body ensures that the activities of subsidiaries, subcontractors and external experts do not affect its independence,		

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	impartiality or objectivity		
13	Documentation on the impartiality of the top-level management and personnel involved in conformity assessment activities, including their remuneration and bonuses		
14	Documentation on conflict of interest and resolution of potential conflict procedure/form		
15	Description of independence of the conformity assessment body from **[**[F38]the Secretary of State**]**		
Confidentiality			
16	Documentation on professional secrecy procedure including protection of proprietary data		
Liability			
17	Documentation of the liability insurance, proof that the liability insurance covers cases where the **[**[F39]approved body**]** may be obliged to withdraw or suspend certificates		
Financial resources			
18	Documentation of the financial resources required to conduct the conformity assessment activities, related operations, including the ongoing commitments for certificates issued		

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	to demonstrate the continuing viability of the **[**[F39]approved body**]** and consistency with the range of products certified		
Quality system			
19	Quality Manual and a list of related documentation on the implementation, maintenance and operation of a quality management system, including policies for assignment of personnel to activities and their responsibilities		
20	Documentation on the procedure(s) for control of documents		
21	Documentation on the procedure(s) for control of records		
22	Documentation on the procedure(s) for management review		
23	Documentation on the procedure(s) for internal audits		
24	Documentation on the procedure(s) for corrective and preventive actions		
25	Documentation on the procedure(s) for complaints and appeals		
Resource requirements			
General			
26	Description of own laboratories and testing facilities		
27	Employment contracts and other		

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	agreements with internal personnel, in particular in relation to impartiality, independence, conflict of interest (attach a standard contract template)		
28	Contracts and other agreements with subcontractors and external experts, in particular for impartiality, independence, conflict of interest (attach a standard contract template)		
Qualification and authorisation of personnel			
29	List of all permanent and temporary personnel (technical, administrative etc.) including information on professional qualification, past experience and the types of contracts held		
30	List of all external personnel (e.g. external experts, external auditors) including information on professional qualification, past experience and on the types of contracts held		
31	Qualification matrix linking the body's staff and its external experts to the functions to be accomplished by them and to the fields of competence for which the body has been **[**[F40]approved**]**		

Changes to legislation: *Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

	or wishes to be **[**[F40]approved**]**		
32	Qualification criteria for the different functions (see point 31)		
33	Documentation on the procedure(s) for selection and assignment of internal or external personnel involved in the conformity assessment activities, including conditions for the attribution of tasks to external personnel and the supervision of their expertise		
34	Documentation demonstrating that the management of the conformity assessment body has appropriate knowledge to set up and operate a system for: — the selection of the personnel deployed during the conformity assessment, — the verification of the knowledge and experience of this personnel, — the assignment of the personnel to their tasks, — the verification		

***Changes to legislation:** Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

	— of the performance of the personnel, the definition and the verification of their initial and ongoing training		
35	Documentation on the procedure assuring ongoing monitoring of competences and performance monitoring		
36	Documentation on standard training programmes conducted by the conformity assessment body relevant to the conformity assessment activities		
Subcontractors			
37	List of all subcontractors (not individual external experts) used for conformity assessment activities		
38	Subcontractor policy and procedure		
39	Documentation demonstrating adequate core competence within the conformity assessment body to assess, select, contract, and to verify the appropriateness and validity of subcontractor activities		

Changes to legislation: *Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

40	Examples of standard template contract, prohibiting further subcontracting by legal persons and specifically including provisions to ensure confidentiality and conflict of interest management with subcontractors (attach examples)		
Process			
41	Documentation on procedures relating to conformity assessment activities and other related documents reflecting the scope of conformity assessment activities including, in particular procedures relating to: — Qualification and classification — Quality system assessments — Risk management — Pre-clinical data evaluation — Clinical evaluation — Representative sampling of technical documentation — Post-market clinical follow up — **[**[F41]Communications from the Secretary of State or other regulatory authorities**]**		

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	— Communication and analysis of the impact of vigilance reports on device certification — Consultation procedures for drug-device combination products, devices utilising animal tissue, devices utilising human blood derivatives — Review and decision making on certificate issuance including approval responsibilities — Review and decision making on certificate suspension, restriction, withdrawal and refusal including approval responsibilities		
42	Checklists, templates, reports and certificates used for the conformity assessment activities		

Changes to legislation: *Commission Implementing Regulation (EU) No 920/2013 is up to date with all changes known to be in force on or before 30 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. (See end of Document for details) View outstanding changes*

Textual Amendments

F37 Words in Annex 2 omitted (11.8.2021) by virtue of The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(i)**

F38 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(ii)**

F39 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(iii)**

F40 Word in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(iv)**

F41 Words in Annex 2 substituted (11.8.2021) by The Medical Devices (Amendment) (EU Exit) Regulations 2021 (S.I. 2021/873), reg. 1(1), **Sch. 2 para. 32(c)(v)**

Name and signature of an authorised representative of the applicant conformity assessment body (unless electronic signature is accepted)		Place and date

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(**1**) OJ L 189, 20.7.1990, p. 17.

(**2**) OJ L 169, 12.7.1993, p. 1.

(**3**) OJ L 218, 13.8.2008, p. 30.

(**4**) OJ L 218, 13.8.2008, p. 82.

(**5**) **[**[F20]Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions (OJ L 130, 24.4.2020, p. 18).**]**

(**6**) **[**[F20]Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).**]**

(**7**) See Annex II Item 41.

Textual Amendments

F20 Inserted by Commission Implementing Regulation (EU) 2020/666 of 18 May 2020 amending Implementing Regulation (EU) No 920/2013 as regards the renewal of designations and the surveillance and monitoring of notified bodies (Text with EEA relevance).

Changes to legislation:
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View outstanding changes

Changes and effects yet to be applied to :

– Regulation revoked by S.I. 2002/618, reg. 4L(1)(2) (as inserted) by S.I. 2019/791 reg. 3(7)