ANNEX I

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:

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 **[**F1UK responsible person**]**, a supplier or a commercial competitor as regards F2... 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. F3...

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.

Textual Amendments

F1 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)**

F2 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)**

F3 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:

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:

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[(1)] 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

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:

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.

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:

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

Application form to be submitted when applying for designation as [F4an approved] body

Textual Amendments

F4 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): …

[F5Approved**]** Body number (if applicable): …

Textual Amendments

F5 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: …

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) **F6** ...		
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		

	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,		

	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 **[**[F7]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 **[**[F8]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		

	to demonstrate the continuing viability of the **[**[F8]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		

	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 **[**[F9]approved**]**		

	or wishes to be **[**[F9]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		

	— 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		

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 — **[**[F10]Communications from the Secretary of State or other regulatory authorities**]**		

	— 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		

Textual Amendments

F6 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)**

F7 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)**

F8 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)**

F9 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)**

F10 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

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

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 09 October 2023. 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.
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)