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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 **[**[F1]UK 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.

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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

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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:

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:

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.

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

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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)