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: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) No 920/2013. Any changes that have already been made to the legislation 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:

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Article 1

Definitions

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

(a) ‘device’ means active implantable medical devices as defined in Article 1(2)(c) of Directive 90/385/EEC or medical devices and their accessories as defined in Article 1(2) of Directive 93/42/EEC;

(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) ‘notified body’ means a conformity assessment body which has been notified by a Member State in accordance with Article 11 of Directive 90/385/EEC or Article 16 of Directive 93/42/EEC;

(d) ‘accreditation body’ means the sole body in a Member State that performs accreditation with authority derived from the State as laid down by Article 2(10) of Regulation (EC) No 765/2008;

(e) ‘designating authority’ means the authority(ies) entrusted by a Member State to assess, designate, notify and monitor notified bodies under Directive 90/385/EEC or Directive 93/42/EEC;

(f) ‘competent authority’ means the authority(ies) in charge of market surveillance and/or of vigilance for devices;

(g) ‘on-site assessment’ means a verification in the premises of the body or of one of its subcontractors or subsidiaries by the designating authority;

(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 a designating authority'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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Article 2

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

Procedure for the designation of notified bodies

1 When applying for designation as a notified 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 notified, the latter by indicating the codes used in the 'New Approach Notified and Designated Organisations' Information System[(5)] and subdivisions of those fields.

2 The designating authority of the Member State where the conformity assessment body is established 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.

Representatives of designating authorities of two other Member States shall, in coordination with the designating authority of the Member State in which the conformity assessment body is established and together with a representative of the Commission, participate to the assessment of the conformity assessment body, including the on-site assessment. The designating authority of the Member State where the conformity assessment body is established shall give those representatives timely access to the documents necessary to assess the conformity assessment body. They shall produce within 45 days after the on-site assessment a report, which shall contain at least a summary of identified non-compliances with the criteria set out in Annex I and recommendation with regard to the designation of the notified body.

3 The Member States shall make available a pool of assessors for the Commission to call upon for each assessment.

4 The designating authority of the Member State where the conformity assessment body is established shall upload into a data storage system managed by the Commission, the assessment report drafted by the representatives referred to in paragraph 2, its own assessment report and, if not contained therein, an on-site assessment report.

5 The designating authorities of all the other Member States shall be informed of the application and may request to get access to certain or all the documents referred to in paragraph 4. Those authorities and the Commission may review all the documents referred to in paragraph 4, may raise questions or concerns and may request further documentation within one month after the last upload of one of those documents. Within the same period of time, they may request an exchange of views on the application, organised by the Commission.