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)

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[(1)] 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.

6 The designating authority of the Member State where the conformity assessment body is established shall respond to the questions, concerns and requests for further documentation within four weeks following their receipt.

The designating authorities of the other Member States or the Commission may individually or jointly address recommendations to the designating authority of the Member State where the conformity assessment body is established within four weeks following the receipt of the response. That designating authority shall take account of the recommendations when it takes the decision on the designation of the conformity assessment body. If it does not follow the recommendations, it shall give the reasons therefor within two weeks after its decision.

7 The Member State shall notify to the Commission its decision on the designation of a conformity assessment body by means of the 'New Approach Notified and Designated Organisations' Information System.

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

(**1**) ‘NANDO’; see http://ec.europa.eu/enterprise/newapproach/nando