ANNEX IX

CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM AND ON ASSESSMENT OF TECHNICAL DOCUMENTATION

CHAPTER I

QUALITY MANAGEMENT SYSTEM

1. The manufacturer shall establish, document and implement a quality management system, as described in Article 10(8), and maintain its effectiveness throughout the life cycle of the devices concerned. The manufacturer shall ensure the application of the quality management system as specified in Section 2, and shall be subject to audit as laid down in Sections 2.3 and 2.4 and to surveillance as specified in Section 3.

2. Quality management system assessment

2.1. The manufacturer shall lodge an application for assessment of its quality management system with a notified body. The application shall include:

— the name of the manufacturer and address of its registered place of business and any additional manufacturing site covered by the quality management system, and, if the manufacturer's application is lodged by its authorised representative the name of the authorised representative and the address of the authorised representative's registered place of business,

— all relevant information on the device or group of devices covered by the quality management system,

— a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,

— a draft of an EU declaration of conformity in accordance with Article 17 and Annex IV for the device model covered by the conformity assessment procedure,

— the documentation on the manufacturer's quality management system,

— a documented description of the procedures in place to fulfil the obligations arising from by the quality management system and required under this Regulation and of the undertaking by the manufacturer in question to apply those procedures,

— a description of the procedures in place to ensure that the quality management system remains adequate and effective, and the undertaking by the manufacturer to apply those procedures,

— the documentation on the manufacturer's post-market surveillance system, and, where applicable, on the PMPF plan, and the procedures put in place to ensure compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87,

— a description of the procedures in place to keep up to date the post-market surveillance system and, where applicable, the PMPF plan, and the procedures ensuring compliance with the obligations resulting from the provisions on vigilance set out in Articles 82 to 87, as well as the undertaking by the manufacturer to apply those procedures,

— documentation on the performance evaluation plan, and

— a description of the procedures in place to keep up to date the performance evaluation plan, taking into account the state of the art.

2.2. Implementation of the quality management system shall ensure compliance with this Regulation. All the elements, requirements and provisions adopted by the manufacturer for its quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans and quality records.

Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:

(a) the manufacturer's quality objectives;

(b) the organisation of the business and in particular:
- the organisational structures with the assignment of staff responsibilities in relation to critical procedures, the responsibilities of the managerial staff and their organisational authority,
- the methods of monitoring whether the operation of the quality management system is efficient and in particular the ability of that system to achieve the desired design and device quality, including control of devices which fail to conform,
- where the design, manufacture, and/or final verification and testing of the devices, or parts of any of those processes, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,
- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention from the authorised representative to accept the mandate;

(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques. Those procedures and techniques shall specifically cover:
- the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence, choice of, and compliance with, conformity assessment procedures,
- identification of applicable general safety and performance requirements and solutions to fulfil those requirements, taking applicable CS into account and, where opted for, harmonised standards,
- risk management as referred to in Section 3 of Annex I,
- the performance evaluation, pursuant to Article 56 and Annex XIII, including PMPF,
- solutions for fulfilling the applicable specific requirements regarding design and construction, including appropriate pre-clinical evaluation, in particular the requirements of Chapter II of Annex I,
- solutions for fulfilling the applicable specific requirements regarding the information to be supplied with the device, in particular the requirements of Chapter III of Annex I,
- the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture, and

— management of design or quality management system changes;

(d) the verification and quality assurance techniques at the manufacturing stage and in particular the processes and procedures which are to be used, particularly as regards sterilisation, and the relevant documents, and

(e) the appropriate tests and trials which are to be carried out before, during and after manufacture, the frequency with which they are to take place, and the test equipment to be used; it shall be possible to trace back adequately the calibration of that test equipment.

In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annexes II and III.

2.3. Audit

The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 2.2. Where the manufacturer uses a harmonised standard or CS related to a quality management system, the notified body shall assess conformity with those standards or CS. The notified body shall assume that a quality management system which satisfies the relevant harmonised standards or CS conforms to the requirements covered by those standards or CS, unless it duly substantiate not doing so.

The audit team of the notified body shall include at least one member with past experience of assessments of the technology concerned in accordance with Sections 4.3. to 4.5. of Annex VII. In circumstances where such experience is not immediately obvious or applicable, the notified body shall provide a documented rationale for the composition of that team. The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.

Moreover, in the case of class C devices, the quality management system assessment shall be accompanied by the assessment of the technical documentation for devices selected on a representative basis in accordance with provisions in Sections 4.4 to 4.8. In choosing representative samples the notified body shall take into account the published guidance developed by the MDCG pursuant to Article 99 and in particular, the novelty of the technology, the potential impact on the patient and standard medical practice, similarities in design, technology, manufacturing and, where applicable, sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation. The notified body in question shall document its rationale for the samples taken.

If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate. The notified body shall notify the manufacturer of tits decision to issue the certificate. The decision shall contain the conclusions of the audit and a reasoned report.

2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether, after those changes, the quality management system still meets the requirements referred to in Section 2.2. It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any substantial change to the quality management system

or the device-range covered shall take the form of a supplement to the EU quality management system certificate.

3. Surveillance assessment applicable to class C and class D devices

3.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the obligations arising from the approved quality management system.

3.2. The manufacturer shall give authorisation to the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:

— the documentation on its quality management system,

— the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the PMPF plan, for a representative sample of devices, and of the provisions on vigilance set out in Articles 82 to 87,

— the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 4 of Annex I,

— the data stipulated in the part of the quality management system relating to manufacture, such as quality control reports and test data, calibration data, and records on the qualifications of the personnel concerned.

3.3. Notified bodies shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer in question applies the approved quality management system and the post-market surveillance plan. Those audits and assessments shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors. At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with a surveillance audit report and, if a test has been carried out, with a test report.

3.4. The notified body shall randomly perform at least once every five years unannounced audits on the site of the manufacturer and, where appropriate, the site of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 3.3 or be performed in addition to that surveillance assessment. The notified body shall establish a plan for such unannounced on-site audits but shall not disclose it to the manufacturer.

Within the context of such unannounced on-site audits, the notified body shall test an adequate sample of the devices produced or an adequate sample from the manufacturing process to verify that the manufactured device is in conformity with the technical documentation. Prior to unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.

Instead of, or in addition to, sampling referred to in the second paragraph, notified bodies shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation. Prior to the sampling, the notified body in question shall specify the relevant sampling criteria and testing procedure.

The notified body shall provide the manufacturer in question with an on-site audit report which shall include, if applicable, the result of the sample test.

3.5. In the case of class C devices, the surveillance assessment shall also include an assessment of the technical documentation as referred to in Sections 4.4 to 4.8 of for

the device or devices concerned on the basis of further representative samples chosen in accordance with the rationale documented by the notified body in accordance with the third paragraph of Section 2.3.

3.6. Notified bodies shall ensure that the composition of the assessment team is such that there is sufficient experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals. As a general rule, a lead auditor shall neither lead nor attend audits for more than three consecutive years in respect of the same manufacturer.

3.7. If the notified body finds a divergence between the sample taken from the devices produced or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.

CHAPTER II

ASSESSMENT OF THE TECHNICAL DOCUMENTATION

4. Assessment of the technical documentation of class B, C and D devices and batch verification applicable to class D devices

4.1. In addition to the obligation laid down in Section 2, the manufacturer of devices shall lodge with the notified body an application for the assessment of the technical documentation relating to the device which it plans to place on the market or put into service and which is covered by the quality management system referred to in Section 2.

4.2. The application shall describe the design, manufacture and performance of the device in question. It shall include the technical documentation as referred to in Annexes II and III.

In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in point (b) of Section 5.1.

4.3. The notified body shall examine the application by using staff, employed by it, with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.

4.4. The notified body shall review the clinical evidence presented by the manufacturer in the performance evaluation report and the related performance evaluation that was conducted. The notified body shall use employed device reviewers with sufficient clinical expertise and including external clinical experts with direct and current experience relating to the clinical application of the device in question for the purposes of that review.

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors

such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity.

4.6. The notified body shall verify that the clinical evidence and the performance evaluation are adequate and shall verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements. That verification shall include consideration of the adequacy of the benefit-risk determination, the risk management, the instructions for use, the user training and the manufacturer's post-market surveillance plan, and include a review of the need for, and the adequacy of, the PMPF plan proposed, where applicable.

4.7. Based on its assessment of the clinical evidence, the notified body shall consider the performance evaluation and the benefit-risk determination, and whether specific milestones need to be defined to allow the notified body to review updates to the clinical evidence that result from post-market surveillance and PMPF data.

4.8. The notified body shall clearly document the outcome of its assessment in the performance evaluation assessment report.

4.9. Before issuing an EU technical documentation assessment certificate, the notified body shall request an EU reference laboratory, where designated in accordance with Article 100, to verify the performance claimed by the manufacturer and the compliance of the device with the CS, where available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. The verification shall include laboratory tests by the EU reference laboratory as referred to in Article 48(5).

In addition, the notified body shall, in the cases referred to in Article 48(6) of this Regulation, consult the relevant experts referred to in Article 106 of Regulation (EU) 2017/745 in accordance with the procedure laid down in Article 48(6) of this Regulation on the performance evaluation report of the manufacturer.

The EU reference laboratory shall provide a scientific opinion within 60 days.

The scientific opinion of the EU reference laboratory and, where applicable, the views of the experts consulted, pursuant to the procedure laid down in Article 48(6), and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall, when making its decision, give due consideration to the views expressed in the scientific opinion of the EU reference laboratory, and, where applicable, to the views expressed by the experts consulted pursuant to Article 48(6). The notified body shall not deliver the certificate if the scientific opinion of the EU reference laboratory is unfavourable.

4.10. The notified body shall provide the manufacturer with a report on the technical documentation assessment, including a performance evaluation assessment report. If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the technical documentation assessment, the conditions of the certificate's validity, the data needed for identification of the approved device, and, where appropriate, a description of the intended purpose of the device.

4.11. Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes it shall inform the notified body which issued the EU technical

documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

Where the changes could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate, the notified body shall consult the EU reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS or with other solutions chosen by the manufacturer, to ensure a level of safety and performance that is at least equivalent, is maintained.

The EU reference laboratory shall provide a scientific opinion within 60 days.

4.12. To verify conformity of manufactured class D devices, the manufacturer shall carry out tests on each manufactured batch of devices. After the conclusion of the controls and tests, it shall forward to the notified body, without delay, the relevant reports on those tests. Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and detailed arrangements which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to the EU reference laboratory, where such a laboratory has been designated in accordance with Article 100, to carry out appropriate tests. The EU reference laboratory shall inform the notified body about its findings.

4.13. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed timeframe, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.

5. Assessment of the technical documentation of specific types of devices

5.1. Assessment of the technical documentation of class B, C and D devices for self-testing and near-patient testing

(a) The manufacturer of class B, C and D devices for self-testing and near-patient testing shall lodge with the notified body an application for the assessment of the technical documentation.

(b) The application shall enable the design of the device characteristics and performance(s) to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:

(i) test reports, including results of studies carried out with intended users;

(ii) where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;

(iii) data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing;

(iv) the information to be provided with the device on its label and its instructions for use.

The notified body may require the application to be completed by carrying out further tests or by providing further proof to allow assessment of conformity with the requirements of this Regulation.

(c) The notified body shall verify the compliance of the device with the relevant requirements set out in Annex I of this Regulation.

(d) The notified body shall assess the application, by using staff, employed by it, with proven knowledge and experience regarding the technology concerned and the intended purpose of the device and provide the manufacturer with a technical documentation assessment report.

(e) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of its validity, the data needed for the identification of the approved devices and, where appropriate, a description of the intended purpose of the device.

(f) Changes to the approved device shall require approval from the notified body which issued the EU technical documentation assessment certificate, where such changes could affect the safety and performance of the device or the conditions prescribed for use of the device. Where the manufacturer plans to introduce any of the above-mentioned changes, it shall inform the notified body which issued the EU technical documentation assessment certificate thereof. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide it with a supplement to the EU technical documentation assessment certificate.

5.2. Assessment of the technical documentation of companion diagnostics

(a) The manufacturer of a companion diagnostic shall lodge with the notified body an application for the assessment of the technical documentation. The notified body shall assess that application in accordance with the procedure laid down in Sections 4.1 to 4.8 of this Annex.

(b) The application shall enable the characteristics and performance of the device to be understood, and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.

(c) The notified body shall, before issuing an EU technical documentation assessment certificate for the companion diagnostic and on the basis of the draft summary of safety and performance and the draft instructions for use, seek a scientific opinion from one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or from the EMA, either of which to be referred to in this Section as ‘the medicinal products authority consulted’ depending on which has been consulted under this point, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex to Regulation (EC) No 726/2004 of the European Parliament and of the Council[(1)], the notified body shall seek the opinion of the EMA. If the medicinal product concerned is already authorised, or if an application for its authorisation has

been submitted, the notified body shall consult the medicinal products authority, or the EMA, that is responsible for the authorisation.

(d) The medicinal products authority consulted shall provide its opinion, within 60 days of receipt of all the necessary documentation. This 60-day period may be extended once for a further 60 days on justified grounds. The opinion and any possible update shall be included in the documentation of the notified body concerning the device.

(e) The notified body shall give due consideration to the scientific opinion referred to in point (d) when making its decision. The notified body shall convey its final decision to the medicinal products authority consulted. The EU technical documentation assessment certificate shall be delivered in accordance with point (e) of Section 5.1.

(f) Before changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 48 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case, the notified body shall assess the changes and seek the opinion of the medicinal products authority consulted. The medicinal products authority consulted shall give its opinion within 30 days of receipt of the all the necessary documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (f) of Section 5.1.

CHAPTER III

ADMINISTRATIVE PROVISIONS

6. The manufacturer or, where the manufacturer does not have a registered place of business in a Member State, it's authorised representative shall, for a period ending no sooner than 10 years after the last device has been placed on the market, keep at the disposal of the competent authorities:

— the EU declaration of conformity,

— the documentation referred to in the fifth indent of Section 2.1. and, in particular, the data and records arising from the procedures referred to in point (c) of the second paragraph of Section 2.2.,

— information on the changes referred to in Section 2.4.,

— the documentation referred to in Sections 4.2. and point (b) of Section 5.1., and

— the decisions and reports from the notified body as referred to in this Annex.

7. Each Member State shall require that the documentation referred to in Section 6 is kept at the disposal of competent authorities for the period indicated in that Section in case a manufacturer, or its authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of that period.

(**1**) Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).