MEDICINES CONTROL COUNCIL

DEPARTMENT OF HEALTH
Republic of South Africa

MEDICINES CONTROL COUNCIL

CONFORMITY ASSESSMENT PROCEDURES
MEDICAL DEVICES and IVDs

This guideline is intended to provide recommendations to applicants wishing to submit applications for the registration of medical devices and IVDs. It represents the Council's current thinking on the safety, quality and performance of medical devices and IVDs. It is not intended as an exclusive approach. The council reserves the right to request any additional information to establish the safety, quality and performance of a medical device or IVD in keeping with the knowledge current at the time of evaluation. Alternative approaches may be used but these should be scientifically and technically justified. The Council is committed to ensure that all registered medical devices and IVDs will be of the required quality, safety and performance. It is important that applicants adhere to the administrative requirements to avoid delays in the processing and evaluation of applications.

Guidelines and application forms are available from the office of the Registrar and the website.

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REGISTRAR

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CONFORMITY ASSESSMENT PROCEDURES FOR MEDICAL DEVICES AND IVDs

NOTE: These guidelines outline the format and data requirements for preparation and submission of an application for registration of Medical Devices and IVDs, and should be read in conjunction with the Medicines and Related Substances Act, 1965 (Act 101 of 1965), and the Regulations to this Act.

A CONFORMITY ASSESSMENT

CONFORMITY ASSESSMENT OVERVIEW

Conformity assessment, conducted before and after a medical device is placed on the market, and post-market surveillance of devices in use are complementary elements of the South African regulatory model. It is intended to provide the objective evidence of safety, performance, and benefits and risks to maintain public and professional confidence.

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, for devices sold in South Africa - it is undertaken in the context of the South African regulatory requirements and both the process and conclusions may be subject to further review by the Council and/or the Conformity Assessment Body accredited by SANAS and approved by the Council.

The purpose of this guideline is to provide guidance on:

- the evidence and procedures that may be used by the manufacturer to demonstrate that a medical device is safe and performs as intended.
- the conformity assessment elements that apply to each class of device such that the requirements increase with the hazard presented by a particular medical device;
- the process by which the Conformity Assessment Body and Council may confirm that such elements are properly applied by the manufacturer; and
- the manufacturer's written attestation that it has correctly applied the conformity assessment elements relevant to the classification of the device, i.e. the 'Declaration of Conformity'.

The following definitions apply:

Audit: Systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

Audit Criteria: Set of policies, procedures or requirements.

Audit Evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable. *NOTE: Audit evidence may be qualitative and/or quantitative and is used to substantiate audit observations.*

"Conformity Assessment" means the systematic examination of evidence generated and procedures undertaken by the manufacturer, to determine that a medical device is safe and performs as intended and conforms to the Essential Principles of Safety and Performance for Medical Devices as determined by the Council;

"Conformity Assessment Body" means a body corporate or other legal entity, locally or internationally, accredited by SANAS or an international body recognized by Council, according to a standard as determined by the Council, as competent to carry out the assessment, verification and certification of medical devices or IVDs before they are placed on the market by manufacturers;

The Conformity Assessment Body (CAB) is engaged in determining whether the relevant requirements in technical regulations or standards are fulfilled. Council may approve conformity assessment and certification to recognised standards by specific international Conformity Assessment Bodies.

Recognised Standards: Local South African and international standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Summary Technical Documentation (STED): A summary of technical documentation held or submitted for conformity assessment purposes.

Technical Documentation: The documented evidence, normally an output of the quality management system that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*.

The application of the conformity assessment procedures to a medical device, IVD, or a kind of medical device, is set out in this Guideline.

Conformity Assessment applies to all classes of medical devices and IVDs as noted in this guideline.

The manufacturer of a device must apply to the device appropriate conformity assessment procedures, being:

(a) the minimum conformity assessment procedures that are applicable, under this Guideline, to the device; or

(b) if the manufacturer prefers, conformity assessment procedures that are applicable, under this Guideline, to a medical device that is classified at a higher level than the device concerned.

For the purpose of applying conformity assessment procedures to a kind of medical device or IVD, a function of the Conformity Assessment Body, in relation to an assessment to be conducted under the procedures, may be exercised or performed at the place where the manufacturer is located, and at the manufacturing site, by a body or authority that the Council is satisfied has the authority and expertise to exercise that power or perform that function.

If, under the conformity assessment procedures, the manufacturer of the kind of medical device is required to give additional information to the Council, the information must be given to the Council in addition to any such information that is given to the accredited Conformity assessment Body mentioned above.

B CONFORMITY ASSESSMENT PROCEDURES

1 PART 1—FULL QUALITY ASSURANCE PROCEDURES

1.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a medical device:

(1) to:

(a) implement a quality management system for the design, production, packaging, labelling and final inspection of the type of device; and

(b) arrange for assessment of the system by a Conformity Assessment Body; and

(2) for a Class D IVD medical device and Class D medical device - to arrange for examination of the design of the kind of device by the Conformity Assessment Body; and

(3) to allow the Conformity Assessment Body to monitor the operation of, and carry out inspections of, the system; and

(4) to make a declaration of conformity in relation to the kind of device; and

(5) to:

(a) notify the Conformity Assessment Body of any change to the system, or to the kinds of devices to which the system is to be applied; and

(b) arrange for assessment of any such change by the Conformity Assessment Body; and

(6) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

1.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

1.3 Implementation and assessment of quality management system

(1) The manufacturer of a kind of medical device must:

(a) implement a quality management system for the design, production, packaging, labelling and final inspection of the kind of device; and

(b) arrange for assessment of the system by the Conformity Assessment Body.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kind of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) an undertaking by the manufacturer to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 1.4(3)(c)(i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

1.4 Requirements of quality management system

(1) A quality management system that is to be assessed under clause 1.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device to which the system is applied complies with the applicable provisions of the essential principles, the classification rules, and these conformity assessment procedures, at each stage, from the design of the device until its final inspection before being supplied.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained, post- production, in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the kind of device; or
- any inadequacy in the design, production, labelling or instructions for use of the kind of device, or in the advertising material for the kind of device; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the design and production of medical devices manufactured by the manufacturer;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of design and product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the design of the kind of medical device to which the system is to be applied, including, in particular, the following:

(i) details of the processes, systems and measures used for controlling, monitoring and verifying that at each stage of the design process, the device complies with the applicable provisions of the essential principles;

(ii) a general description of the kind of device, and of any variants of the kind of device, that the manufacturer plans to manufacture;

(iii) details of the design specifications for the kind of device, including:

- any medical device standard or conformity assessment standard that has been applied to the device; and
- the results of the risk analysis carried out; and
- if no medical device standard or conformity assessment standard, or part only of such a standard, has been applied to the device—the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(iv) for a kind of device that is intended by the manufacturer to be connected to another device—evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(v) a statement indicating whether or not the kind of device incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a device that will do so, data derived from tests conducted in relation to the device and the substance, and their interaction;

(vi) a statement indicating whether or not the device, other than an IVD medical device, contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(vii) for an IVD medical device—a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

(viii) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(ix) a copy of the information to be provided with the kind of device;

(d) the inspection and quality assurance techniques to be applied in the production of the kind of medical device to which the system is to be applied, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those processes and procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of production;

(e) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(f) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(g) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system—the solutions adopted to ensure that the system complies with subclause (2).

1.5 Changes to quality management system or kinds of medical device to which system is to be applied

(1) This clause applies to the manufacturer of a kind of medical device if:

(a) the manufacturer has implemented, and had assessed under clause 1.3, a quality management system that is to be applied to the kind of device; and

(b) after assessment, the manufacturer plans to make:

(i) a substantial change to the system; or

(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:

(a) notify the Conformity Assessment Body, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Conformity Assessment Body to verify whether the system, as changed, meets the requirements of clause 1.4.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 1.3(2) in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 1.4.

1.6 Examination of design of Class D IVD medical device, or Class D medical device

(1) This clause applies to the manufacturer of a Class D IVD medical device, or a Class D medical device, to which the quality management system that is to be assessed under clause 1.3 is to be applied.

(2) For the purpose of assessing whether the kind of medical device complies with the applicable provisions of the essential principles, the manufacturer of the device must arrange for examination by the Conformity Assessment Body of the design of the kind of device.

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available:

(a) information, in writing, in relation to the following matters in relation to the kind of medical device:

(i) the design;

(ii) the production process;

(iii) the intended performance; and

(b) a copy of the documentation mentioned in paragraph 1.4(5)(c) necessary to assess whether the kind of medical device complies with the applicable provisions of the essential principles.

(4) If, after examination by the Conformity Assessment Body of the design of a kind of medical device, the manufacturer makes a substantial change to the design, or the intended performance, of the kind of device, the manufacturer must:

(a) notify the Conformity Assessment Body, in writing, of the change; and

(b) arrange for examination of the change by the Conformity Assessment Body to assess whether the design, or the intended performance, of the medical device, as changed, complies with the applicable provisions of the essential principles.

(5) For the purpose of enabling an examination to be carried out under subclause (4), the manufacturer must have available, in writing, details of any consequential changes to the documentation in relation to the design of the device mentioned in paragraph 1.4(5)(c).

Note: This clause need not be applied to:

(a) a Class C medical device; or

(b) a Class C IVD medical device; or

(c) a Class B medical device; or

(d) a Class B IVD medical device.

1.7 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a kind of medical device must:

(a) give to the Conformity Assessment Body the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 1.4(5);

(ii) data in relation to the design of the kinds of medical device (for example, the results of any analysis of the device, calculations, tests);

(iii) data in relation to the manufacture of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices produced by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

1.8 Declaration of conformity

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 has been applied must make a declaration of conformity in relation to the kind of device.

(2) (The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 1.8 of Conformity Assessment Procedures to the *Medical Device& IVD Regulations R……. 20XX*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules, and the full quality assurance procedures, at each stage, from the design of the device until its final inspection before being supplied; and

(f) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside South Africa in relation to the system or the kind of medical devices to which the system has been applied; and

(g) give details of any conformity assessment standard or medical device standard that has been applied to a kind of device to which the system has been applied; and

(h) be signed by a person authorised by the manufacturer; and

(i) set out the name and position of the person signing the declaration; and

(j) state the date when the declaration is signed.

1.9 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 1.3 has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 1.4(5);

(b) details of any changes made to the system and to the information and documentation required under subclause 1.3(2);

(c) if the device is a Class D IVD medical device, or Class D medical device, the information and documentation required under subclause 1.6(3);

1.9 Records - continued

(d) details of any changes made to the kind of medical device and to the documentation in relation to the design of the device mentioned in paragraph 1.4(5)(c);

(e) the declaration of conformity under clause 1.8;

(f) details of the systematic review carried out, post- production, in relation to medical devices of that kind;

(g) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Conformity Assessment Body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

2 PART 2—TYPE OF EXAMINATION PROCEDURES

2.1 Overview

The conformity assessment procedures set out in this Part provides for the manufacturer to arrange for examination by the Conformity Assessment Body of a representative sample of a kind of medical device (the ***type***).

2.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

2.3 Examination of type

(1) The manufacturer of a medical device must arrange for examination of the type by the Conformity Assessment Body.

(2) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, the following information:

(a) the name and business address of the manufacturer;

(b) the documentation mentioned in subclause (3) in relation to the type.

(3) For paragraph (2)(b), the documentation must include adequate information about the design, production process and intended performance of the type, and must include, in particular, the following:

(a) a general description of the type, and of any variants of the type that the manufacturer plans to manufacture;

(b) diagrams or drawings of the design of the type, including diagrams or drawings of any components, sub-assemblies or circuits of the type;

(c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the type, to be properly understood;

(d) the proposed method or methods of manufacture of the type;

(e) if the type is intended by the manufacturer to be supplied in a sterile state—a description of the method used to sterilise the type;

(f) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the type;

(g) if no medical device standard or conformity assessment standard has been applied, or such a standard has been only partly applied, to the type—descriptions of the solutions adopted to ensure that the type complies with the applicable provisions of the essential principles;

(h) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the type;

(i) a statement indicating whether or not the type incorporates, or is intended to incorporate, as an integral part, a substance mentioned in clause 7.4 of the essential principles, and, for a type that does so, data derived from tests conducted in relation to the type and the substance, and their interaction;

(j) a statement indicating whether or not the device, other than an IVD medical device, contains tissues, cells or substances of animal origin that have been rendered non-viable, or tissues, cells or substances of microbial or recombinant origin;

(k) for an IVD medical device—a statement indicating whether or not the device contains viable tissues, cells, or substances of human or animal origin;

(l) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(m) a copy of the information to be provided with the type.

(4) The manufacturer must make available to the Conformity Assessment Body for examination:

(a) a sample of the type; and

(b) on request from the Conformity Assessment Body, additional samples of the type.

(5) If the type is intended by the manufacturer to be connected to another medical device, the manufacturer must, on request from the Conformity Assessment Body, make available to the Conformity Assessment Body, or arrange for the Conformity Assessment Body to have access to, a sample of the device.

2.4 Changes to design of medical device after examination

(1) This clause applies if, after examination by the Conformity Assessment Body of a type, the manufacturer of the type plans to make a substantial change to the design, or intended performance, of the kind of medical device to which the type relates.

(2) The manufacturer must:

(a) notify the Conformity Assessment Body, in writing, of the proposed change; and

(b) arrange for examination of the change by the Conformity Assessment Body to verify whether the type, as changed, meets the requirements of clause 2.3 .

(3) For the purpose of enabling the examination to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the documentation required under subclause 2.3(3) in relation to the type.

2.5 Records

(1) The manufacturer of the type that has been examined under this Part must keep the following records:

(a) the documentation required under subclause 2.3(3) in relation to the type;

(b) details of any changes made to the type and to the documentation required under subclause 2.3(3) ;

(c) any notice, report, certificate or other document in relation to the type issued to the manufacturer by the Conformity Assessment Body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device of that type.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

3 PART 3—VERIFICATION PROCEDURES

3.1 OVERVIEW

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(1) to arrange for examination and testing of the kind of device by the Conformity Assessment Body; and

(2) to make a declaration of conformity in relation to the kind of device; and

(3) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

3.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

3.3 Verification of conformity

(1) The manufacturer of a medical device must arrange for examination and testing by the Conformity Assessment Body of each device of that kind, or a representative sample from a batch of medical devices of that kind, to verify that:

(a) for a kind of device in relation to which the type examination procedures have been applied—each device, or representative sample, conforms to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—each device, or representative sample, is in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device; and

(c) each device, or representative sample, complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling the examination and testing to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) the documentation describing the manufacturing process to be used to manufacture the kind of device;

(c) a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

(d) an undertaking to implement those procedures to ensure that all devices of that kind manufactured by the manufacturer will be uniform;

(e) an undertaking by the manufacturer to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 3.4(2)(c)(i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device;

(f) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3(3) of the type examination procedures for the approved type;

(g) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

(3) The manufacturer must make available to the Conformity Assessment Body for examination and testing:

(a) for a kind of device in relation to which the type examination procedures have been applied:

(i) each medical device that is to be verified in relation to the approved type; or

(ii) each medical device selected by the Conformity Assessment Body on a statistical basis from a uniform batch of devices that are to be verified in relation to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied:

(i) each medical device of that kind to which those procedures have been applied; or

(ii) each medical device selected by the Conformity Assessment Body on a statistical basis from a uniform batch of devices of that kind to which those procedures have been applied.

3.4 Requirements of manufacturing system

(1) The manufacturer of a medical device must ensure that:

(a) for a kind of device in relation to which the type examination procedures have been applied—the process used to manufacture the device results in the device conforming to the approved type; and

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—the process used to manufacture the device results in the device being in accordance with the technical documentation prepared under clause 6.4 of those procedures for that kind of device.

3.4 Requirements of manufacturing system - continued

(2) The manufacturer of a medical device of a kind mentioned in subclause (1) must ensure that the process used to manufacture the device includes post-marketing requirements under which the manufacturer is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the kind of device; or
- any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

(3) Before manufacturing a medical device of a kind mentioned in subclause (1), the manufacturer must prepare documentation describing the manufacturing process to be used to produce the device.

(4) Without limiting subclause (3), the documentation must include a description of the procedures that have been, or will be, implemented to ensure that all devices of that kind manufactured by the manufacturer will be uniform.

3.5 Declaration of conformity

(1) The manufacturer of a Class D medical device or Class C medical device that has been verified under this Part must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied to the device:

(a) a Class B medical device;

(b) a Class A medical device that has a measuring function

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 3.5 of Conformity Assessment Procedures to the *Medical Device& IVD Regulations R……20XX*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each device that has been verified:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the verification does not relate to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the verification relates (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied:

(i) state the conformity assessment certificate number issued in relation to the approved type, and, if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside South Africa in relation to the approved type; and

(ii) state that the kind of device conforms to the approved type; and

(f) state that each kind of medical device or batch of devices complies with the applicable provisions of the essential principles and the classification rules;

(g) state the basis on which the declaration is made; and

(h) give details of any conformity assessment standard or medical device standard that has been applied to the kind of device or the processes used to manufacture the device; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

3.6 Records

(1) The manufacturer of a kind of medical device that has been verified under this Part must keep the following records:

(a) the documentation mentioned in subclause 3.4(3);

(b) for a Class D medical device or Class C medical device—the declaration of conformity under clause 3.5 ;

(c) any notice, report, certificate or other document in relation to the device, or a batch of devices that includes the device, issued to the manufacturer by the Conformity Assessment Body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the verification relates.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

4 PART 4—PRODUCTION QUALITY ASSURANCE PROCEDURES

4.1 Overview

(1) The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(a) to:

(i) implement a quality management system for the production and final inspection of the kind of device; and

(ii) arrange for assessment of the system by the Conformity Assessment Body; and

(b) to allow the Conformity Assessment Body to monitor the operation of, and carry out inspections of, the system; and

(c) to make a declaration of conformity in relation to the kind of device; and

(d) to:

(i) notify the Conformity Assessment Body of any change to the system; and

(ii) arrange for assessment of any such change by the Conformity Assessment Body; and

(e) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

4.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

4.3 Implementation and assessment of production quality management system

(1) The manufacturer of a medical device must:

(a) implement a quality management system for the production and final inspection of the kind of device; and

(b) arrange for assessment of the system by the Conformity Assessment Body.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kinds of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and a copy of the technical documentation required under subclause 2.3(3) of the type examination procedures for the approved type;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 4.4(3)(c)(i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

4.4 Requirements of production quality management system

(1) A quality management system that is to be assessed under clause 4.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that:

(a) each medical device to which the system is applied that is of a kind in relation to which the type examination procedures have been applied conforms to the approved type; and

(b) each medical device to which the system is applied that is of a kind to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures are applied is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the kind of device; or
- any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

(4) Each requirement of the system must be documented in a systematic and orderly way in the form of written policies and procedures (for example, as quality programs, quality plans, quality manuals or quality records).

(5) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(iii) the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the inspection and quality assurance techniques applied in the manufacturing process, including, in particular, information about the following:

(i) the processes and procedures to be used (particularly in relation to sterilisation) and the documents relating to those procedures;

(ii) the procedures to be used for purchasing goods or services in relation to the production of the kind of device produced and the documents relating to those procedures;

(iii) product identification procedures to be prepared and kept up-to-date from drawings, specifications or other documents at each stage of manufacture;

(d) the tests or trials to be carried out before, during and after production of the kind of medical device to which the system is to be applied, including, in particular, information about:

(i) the frequency with which the tests or trials are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) used, or to be used, to carry out the tests or trials;

(e) the system for reviewing experience gained in the post-production phase in relation to the kind of medical device to which the quality management system has been applied, and the means by which any necessary corrective action will be applied in relation to the design or production of such devices;

(f) whether a conformity assessment standard has been applied to the system and, if no conformity assessment standard, or part only of a conformity assessment standard, has been applied to the system—the solutions adopted to ensure that the system complies with subclause (2).

4.5 Changes to production quality management system

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 4.3, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make a substantial change to the system.

(2) The manufacturer must:

(a) notify the Conformity Assessment Body, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Conformity Assessment Body to verify whether the system, as changed, meets the requirements of clause 4.4.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 4.3(2) in relation to the system.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 4.4.

4.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Conformity Assessment Body the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 4.4(5);

(ii) data in relation to the production of the kinds of medical device (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person under this clause, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

4.7 Declaration of conformity

(1) The manufacturer of a Class D medical device, Class D IVD medical device, Class C IVD medical device or Class C medical device to which a quality management system that has been assessed under clause 4.3 has been applied must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices, if the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied to the device:

(a) a Class B medical device;

(b) a Class B IVD medical device;

(c) a Class A medical device that the manufacturer intends to be supplied in a sterile state;

(d) a Class A medical device that has a measuring function.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 4.7 of Conformity Assessment Procedures to the *Medical Device & IVD Regulations R……20XX* and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the medical device classification;

(ii) the device nomenclature system code; and

4.7 Declaration of conformity - continued

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied—state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside South Africa in relation to the system or the kind of medical devices to which the system has been applied; and

(g) state that each kind of medical device to which the system has been applied complies with the applicable provisions of the essential principles, the classification rules and the production quality assurance procedures before being supplied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

4.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 4.3 has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 4.4(5) ;

(b) details of any changes made to the system and to the information and documentation required under subclause 4.5(3);

(c) for a Class D medical device, Class D IVD medical device, or Class C medical device—the declaration of conformity under clause 4.7;

(d) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Conformity Assessment Body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

5 PART 5—PRODUCT QUALITY ASSURANCE PROCEDURES

5.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(1) to:

(a) implement a product quality management system for the final inspection and testing of the kind of device; and

(b) arrange for assessment of the system by the Conformity Assessment Body; and

(2) to allow the Conformity Assessment Body to monitor the operation of, and carry out inspections of, the system; and

(3) to make a declaration of conformity in relation to the kind of device; and

(4) to:

(a) notify the Conformity Assessment Body of any change to the system, or to the kinds of devices to which the system is to be applied; and

(b) arrange for assessment of any such change by the Conformity Assessment Body; and

(5) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

5.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

5.3 Implementation and assessment of product quality management system

(1) The manufacturer of a medical device must:

(a) implement a product quality management system for the final inspection and testing of the kind of device; and

(b) arrange for assessment of the system by the Conformity Assessment Body.

(2) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where the system is to be applied;

(c) all relevant information about the kinds of medical devices to which the system is to be applied;

(d) the documentation in relation to the system;

(e) an undertaking by the manufacturer to continue to comply with the requirements of the system after assessment;

(f) an undertaking by the manufacturer to ensure that the system is at all times adequate and efficacious;

(g) for a kind of device in relation to which the type examination procedures have been applied—evidence that the device conforms to the approved type and the technical documentation required under subclause 2.3(3) of the type examination procedures for the device;

(h) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—a copy of the technical documentation prepared under clause 6.4 of those procedures for that kind of device;

(i) an undertaking by the manufacturer to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 5.4(3)(c)(i) or (ii) that the manufacturer becomes aware of in relation to the kind of medical device.

5.4 Requirements of product quality management system

(1) A quality management system that is to be assessed under clause 5.3 must meet the requirements of this clause.

(2) The system must be of a kind such that its application will ensure that each medical device, or representative sample of each batch of medical devices, is examined and tested to ensure that the device, or representative sample:

(a) for a kind of device in relation to which the type examination procedures have been applied—conforms to the approved type; or

(b) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the device.

(3) The system must include post-marketing requirements under which the manufacturer of a medical device to which the system is applied is required:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the kind of device; or
- any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

(4) The documentation of the system must include adequate information in relation to the following matters:

(a) the manufacturer's quality objectives;

(b) the organisation of the manufacturer's business, including, in particular, a description of the following:

(i) the organisational structure of the business;

(ii) the responsibilities of managerial staff and their authority in relation to the quality of the medical devices manufactured by the manufacturer;

the methods of monitoring whether the system is operating effectively, in particular, whether the desired quality of product is being achieved and how products that fail to meet the desired quality are controlled;

(c) the examinations and tests to be carried out after manufacture, including, in particular, information about:

(i) the frequency with which the examinations and tests are to be carried out; and

(ii) the equipment (including the traceability of the calibration of the equipment) to be used to carry out the examinations and tests;

(d) the quality records to be kept, including, for example, records in relation to inspections, tests, calibration of equipment and qualifications of staff.

5.5 Changes to product quality management system or kinds of medical device

(1) This clause applies to the manufacturer of a medical device if:

(a) the manufacturer has implemented, and had assessed under clause 5.3, a quality management system that is to be applied to the device; and

(b) after assessment, the manufacturer plans to make:

(i) a substantial change to the system; or

(ii) a change to the kinds of medical devices to which the system is to be applied.

(2) The manufacturer must:

(a) notify the Conformity Assessment Body, in writing, of the proposed change; and

(b) arrange for assessment of the change by the Conformity Assessment Body to verify whether the system, as changed, meets the requirements of clause 5.4.

(3) For the purpose of enabling the assessment to be carried out, the manufacturer must have available, in writing, details of any consequential changes to the information and documentation required under subclause 5.3(2) in relation to the system or kinds of devices.

(4) After any change to the quality management system, the manufacturer must ensure that the changed system continues to meet the requirements of clause 5.4.

5.6 Information to be given to authorised person

(1) If requested to do so by an authorised person, the manufacturer of a medical device must:

(a) give to the Conformity Assessment Body any of the following information in relation to the quality management system or the kinds of medical device to which the system is applied:

(i) a copy of the documentation mentioned in subclause 5.4(5);

(ii) the quality records in relation to the final inspection and testing of the kinds of medical device to which the system is applied (for example, inspection reports, test data, calibration data, information about the qualifications of staff); and

(b) arrange for tests specified by the authorised person to be carried out for the purpose of checking whether the quality management system is operating effectively.

(2) If any inspections or tests are carried out by an authorised person in relation to the manufacturer's premises, or medical devices manufactured by the manufacturer, the manufacturer may ask the authorised person to give to the manufacturer a report stating the findings of the inspections or tests.

5.7 Declaration of conformity

(1) The manufacturer of a Class C medical device to which a quality management system that has been assessed under clause 5.3 has been applied must make a declaration of conformity in relation to the kind of device.

Note: This clause need not be applied to the following kinds of medical devices if the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied to the device:

(a) a Class B medical device;

(b) a Class A medical device that has a measuring function

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 5.7 of the Conformity Assessment Procedures of *Medical Device & IVD Regulations R…. 20XX*; and

(b) state the name and business address of the manufacturer of the device; and

(c) state the following information in relation to each kind of medical device to which the system has been applied:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

the device nomenclature system code; and

(d) if the system has not been applied to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the system has been applied (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(e) for a kind of device in relation to which the type examination procedures have been applied—state that:

(i) the type examination procedures have been applied to the kind of device; and

(ii) the kind of device conforms to the approved type; and

(f) for a kind of device to which the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures have been applied—state that the kind of device is in accordance with the technical documentation prepared under clause 6.4 of those procedures for the kind of device; and

5.7 Declaration of conformity

(g) state:

(i) the conformity assessment certificate number issued in relation to the system or the kind of medical devices to which the system has been applied; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside South Africa in relation to the system or the kind of medical devices to which the system has been applied; and

(h) give details of any conformity assessment standard that has been applied to the system; and

(i) be signed by a person authorised by the manufacturer; and

(j) set out the name and position of the person signing the declaration; and

(k) state the date when the declaration is signed.

5.8 Records

(1) The manufacturer of a kind of medical device to which a quality management system that has been assessed under clause 5.3 has been applied must keep the following records in relation to the system and the kind of device:

(a) the documentation mentioned in subclause 5.4(5) ;

(b) details of any changes made to the system and to the information and documentation required under subclause 5.5(3) ;

(c) details of any changes made to the kinds of medical devices to which the system was applied;

(d) for a Class C medical device—the declaration of conformity under clause 5.7:

(e) any notice, report, certificate or other document in relation to the system issued to the manufacturer by the Conformity Assessment Body.

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the quality management system was applied.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

6 PART 6—DECLARATION OF CONFORMITY (NOT REQUIRING ASSESSMENT BY A CONFORMITY ASSESSMENT BODY) PROCEDURES

6.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device:

(1) to prepare technical documentation in relation to the kind of device to enable assessment of the device; and

(2) to make a declaration of conformity in relation to the kind of device; and

(3) to establish and keep up-to-date a post-market monitoring, reporting and corrective action system.

6.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

6.3 Implementation

(1) The manufacturer of a medical device must prepare technical documentation in relation to the kind of device in a form that, if the Council decides to do so, would allow the Conformity Assessment Body to assess whether the device complies with the applicable provisions of the essential principles, the classification rules and these conformity assessment procedures.

(2) For the purpose of enabling an assessment to be carried out, the manufacturer must have available, in writing, the following information and undertakings:

(a) the name and business address of the manufacturer;

(b) details of each manufacturing site where these conformity assessment procedures are to be applied;

(c) all relevant information required to identify the kinds of medical devices to which these conformity assessment procedures are to be applied;

(d) an undertaking by the manufacturer to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, of any information of the kind mentioned in subparagraph 6.5(2)(c)(i) or (ii) that the manufacturer becomes aware of in relation to a kind of medical device.

6.4 Required technical documentation

(1) The technical documentation must include adequate information in relation to the kind of device, and must include, in particular, the following:

(a) a general description of the kind of device, and of any variants of the kind of device that the manufacturer plans to manufacture;

(b) diagrams or drawings of the design of the kind of device, including diagrams or drawings of any components, sub-assemblies or circuits of the kind of device;

(c) any descriptions or explanations that are necessary to enable the diagrams or drawings mentioned in paragraph (b), or the intended operation of the kind of device, to be properly understood;

(d) if the kind of device is intended by the manufacturer to be supplied in a sterile state—a description of the method used to sterilise the kind of device;

(e) details of each medical device standard or conformity assessment standard that has been applied, wholly or in part, to the kind of device;

(f) if no medical device standard or conformity assessment standard has been applied, or a medical device standard or conformity assessment standard has been only partly applied, to the kind of device—the solutions adopted to ensure that each device complies with the applicable provisions of the essential principles;

(g) the results of any design calculations, risk analyses, investigations, technical tests, or any other tests, carried out in relation to the kind of device;

(h) if the kind of device is intended by the manufacturer to be connected to another device—evidence demonstrating that the device will comply with the applicable provisions of the essential principles when it is connected to the other device and both devices are being used for their intended purposes;

(i) a copy of the clinical evidence, in relation to the kind of device, required by the clinical evaluation procedures;

(j) a copy of the information to be provided with the kind of device.

(2) If the manufacturer makes a change to the design or the production of the kind of medical device after the technical documentation has been prepared (for example, because it was necessary to apply corrective action in relation to the kind of device), the manufacturer must revise the technical documentation to take account of the change.

6.5 Post-marketing system

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 applies must establish, and keep up-to-date, a post-marketing system that complies with subclause (2) for use in relation to devices of that kind.

(2) A post-marketing system complies with this subclause in relation to a medical device if the system requires the manufacturer of the device:

(a) to systematically review experience gained in the post-production phase in relation to medical devices of that kind; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the design or production of such devices; and

(c) to notify the Conformity Assessment Body, or the person in relation to whom the kind of device is included in the Register, as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the kind of device; or
- any inadequacy in the design, production, labelling, instructions for use or advertising materials of the kind of device; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the kind of device;

that might lead, or might have led, to the death of a patient or a user of the device, or to a serious deterioration in his or her state of health; or

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover devices of that kind that have been distributed.

6.6 Declaration of conformity

(1) The manufacturer of a kind of medical device to which technical documentation prepared under clause 6.4 applies must make a declaration of conformity in relation to the kind of device.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 6.6 of the Conformity Assessment Procedures to the *Medical Device& IVD Regulations R…. of 20XX*; and

(b) state the name and business address of the manufacturer of the device; and

6.6 Declaration of conformity - continued

(c) state the following information in relation to each kind of medical device to which the technical documentation applies:

(i) the unique product identifier (for example, the product name or model number);

(ii) the medical device classification;

(iii) the device nomenclature system code; and

(d) if the technical documentation applies to a Class B medical device that the manufacturer intends to be supplied in a sterile state or a Class A medical device that the manufacturer intends to be supplied in a sterile state—state that the production quality assurance procedures have also been applied to the device; and

(e) if the technical documentation applies to a Class B medical device that the manufacturer intends to be supplied in a non-sterile state, or a Class A medical device that has a measuring function and that the manufacturer intends to be supplied in a non-sterile state—state which of the following conformity assessment procedures have also been applied to the device:

(i) the verification procedures;

(ii) the production quality assurance procedures;

(iii) the product quality management system procedures; and

(f) if the technical documentation does not apply to all medical devices of that kind manufactured by the manufacturer—give details of the medical devices to which the technical documentation applies (for example, by reference to lot numbers, batches or serial numbers, or by specifying the kinds of medical devices or the times of manufacture); and

(g) state that each kind of medical device to which the technical documentation applies complies with the applicable provisions of the essential principles, the classification rules, and these procedures; and

(h) if the technical documentation applies to any of the following kinds of medical devices:

(i) a Class B medical device;

(ii) a Class B IVD medical device;

(iii) a Class A medical device that the manufacturer intends to be supplied in a sterile state;

(iv) a Class A medical device that has a measuring function;

state:

(i) the conformity assessment certificate number issued in relation to the kind of medical device, or the quality management system that has been applied to the kind of device, as a result of the application to the device of the conformity assessment procedures set out in Part 3, 4 or 5 ; and

(ii) if applicable, the number of, or other identifying reference to, any equivalent approval or certificate (however described) issued outside South Africa in relation to the kind of medical device, or the quality management system that has been applied to the kind of device; and

(iii) give details of any medical device standard or conformity assessment standard that has been applied to the device; and

(iv) be signed by a person authorised by the manufacturer; and

(v) set out the name and position of the person signing the declaration; and

(vi) state the date when the declaration is signed.

6.7 Records

(1) The manufacturer of a medical device to which technical documentation prepared under clause 6.4 applies must keep the following records:

(a) the technical documentation prepared under clause 6.4, including any revisions of the documentation prepared as a result of changes to the design or production of the kind of device;

(b) details of any changes made to the design or production of the kind of medical device and to the documentation required under clause 6.4;

(c) the declaration of conformity under clause 6.6 .

(2) The manufacturer must keep the records for at least 5 years after the manufacture of the last medical device to which the technical documentation prepared clause 6.4 applies.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the records available to the Conformity Assessment Body or Council.

7 PART 7—PROCEDURES FOR MEDICAL DEVICES USED FOR A SPECIAL PURPOSE

7.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a medical device used for a special purpose:

(1) to prepare a written statement containing certain information in relation to the device; and

(2) to prepare and keep up-to-date particular documentation in relation to the device.

7.2 System or procedure packs

(1) The manufacturer of a system or procedure pack must make a declaration of conformity in relation to the system or procedure pack.

(2) The declaration must:

(a) state that the declaration is a declaration of conformity made under clause 7.2 of Conformity Assessment Procedures to the Medical Device & IVD Regulations R…. 20XX; and

(b) state the name and business address of the manufacturer of the system or procedure pack; and

(c) state sufficient information to enable the user to identify the system or procedure pack or, if relevant, the contents of packaging; and

(d) identify each item in the package; and

(e) state that the manufacturer has evidence:

(i) that the relevant conformity assessment procedures have been applied to each medical device in the package; and

(ii) that each medical device in the package complies with the applicable provisions of the essential principles; and

(f) state the registration or listing number for each medicine or other therapeutic goods, or the biological number for each biological, in the package; and

(g) state that each medical device in the package is intended to be used for its original intended purpose, and each medicine, biological or other therapeutic goods in the package is intended to be used within the approved indications for use specified by the manufacturers of those items; and

(h) state

(i) that the mutual compatibility of each medical device, medicine, biological or other therapeutic goods, and any other goods, in the package has been verified in accordance with any instructions for use provided by the manufacturer of each item or the approved indications for use of each item; and

(ii) that the manufacturer has manufactured the system or procedure pack in accordance with those instructions (if any) or indications; and

(i) state that the information supplied with the system or procedure pack for the use of the system or procedure pack includes instructions for use provided by the manufacturer of each item in the package; and

(j) state that the process of manufacturing the system or procedure pack, and the verification and packaging of the system or procedure pack, has been subjected to a documented method of internal control and inspection that ensures the safety, quality, performance and effectiveness of each item in the package; and

(k) if the system or procedure pack is intended by the manufacturer to be supplied in a sterile state—state that the production quality assurance procedures (other than clause 4.7) have been applied to the system or procedure pack in accordance with the manufacturer's instructions for use, or the approved indications for use, of each item in the package; and

(l) be signed by a person authorised by the manufacturer; and

(m) set out the name and position of the person signing the declaration; and

(n) state the date when the declaration is signed.

(3) The manufacturer of a system or procedure pack must establish, and keep up-to-date, a post-marketing system that complies with subclause (4) for use in relation to the system or procedure pack.

(4) A post-marketing system complies with this subclause in relation to a system or procedure pack if the post-marketing system requires the manufacturer of the system or procedure pack:

(a) to systematically review experience gained in the post-production phase in relation to the system or procedure pack; and

(b) to implement appropriate means to apply any necessary corrective action in relation to the production of the system or procedure pack; and

(c) to notify the Conformity Assessment Body as soon as practicable after becoming aware of:

(i) information relating to:

- any malfunction or deterioration in the characteristics or performance of the system or procedure pack; or
- any inadequacy in the production, labelling, instructions for use or advertising materials of the system or procedure pack; or
- any use in accordance with, or contrary to, the use intended by the manufacturer of the system or procedure pack;

that might lead, or might have led, to the death of a patient or a user of the system or procedure pack, or to a serious deterioration in his or her state of health; or

7.2 System or procedure packs - continued

(ii) information relating to any technical or medical reason for a malfunction or deterioration of a kind mentioned in subparagraph (i) that has led the manufacturer to take steps to recover system or procedure packs of that kind that have been distributed.

7.3 Records

(1) The manufacturer must keep the statement and documentation required under the relevant clause in relation to a medical device to which the conformity assessment procedures in this Part have been applied.

(2) The manufacturer must keep the statement and documentation for at least 5 years after the manufacture of the last medical device to which the statement and documentation relates.

(3) On request from the Conformity Assessment Body or Council, the manufacturer must make the statement and documentation available to the Conformity Assessment Body or Council.

8 PART 8—CLINICAL EVALUATION PROCEDURES

8.1 Overview

The conformity assessment procedures set out in this Part provide for the manufacturer of a kind of medical device to obtain and evaluate clinical data in relation to the kind of device.

8.2 References to kinds of medical devices

A reference in this Part to a kind of medical device includes a reference to an individual medical device.

8.3 Obtaining clinical data

(1) The manufacturer of a kind of medical device must obtain clinical data in relation to the device in the form of either or both of the following:

(a) clinical investigation data in accordance with clause 8.4;

(b) a literature review in accordance with clause 8.5.

(2) The manufacturer must ensure that the clinical data obtained takes account of any medical device standard or conformity assessment standard that may apply to the device.

8.4 Clinical investigation data

(1) For clause 8.3, ***clinical investigation data***, in relation to a kind of medical device, includes:

(a) documentation in relation to the design, approval, conduct and results of each investigation carried out by the manufacturer of the device in relation to the use of the device in or on a human body; and

(b) a record of qualitative or quantitative information obtained through observation, measurement, tests or any other means used to assess the operation of the device; and

(c) a written report by an expert in the relevant field, being a report that contains a critical evaluation of all the clinical investigation data held in relation to the device.

(2) The documentation mentioned in paragraph (1)(a) must be in a form that allows the manufacturer to evaluate whether the device complies with the applicable provisions of the essential principles.

(3) The record mentioned in paragraph (1)(b) must be in a form that allows the information in it to be independently assessed and verified.

(4) If clinical investigation data is collected in South Africa, the investigation must have been conducted in accordance with the ethical standards set out in the 'National Statement on Ethical Conduct in Research Involving Humans', published by the National Health and Medical Research Council, as in force from time to time.

(5) If clinical investigation data is collected outside South Africa, the investigation must have been conducted in accordance with the principles of the Declaration of Helsinki, as in force at the time and place where the investigation was conducted.

8.5 Literature review

For clause 8.3, a ***literature review***, in relation to a kind of medical device, includes:

(1) a compilation, prepared using a documented methodology, of published literature and unpublished scientific literature, both favourable and unfavourable, relating to medical devices of that kind, including the following:

(a) expert opinion;

(b) information about the hazards and associated risks arising from the use of the device for its intended purpose, and the foreseeable misuse of the device;

(c) information about the performance of devices of that kind, including a description of the techniques used to examine whether devices of that kind achieve their intended purpose; and

(2) a written report by an expert in the relevant field, being a report that contains a critical evaluation of the compilation of literature mentioned in paragraph (a).

8.6 Evaluation of clinical data

(1) The manufacturer of a kind of medical device must ensure that the clinical data is evaluated by competent clinical experts.

(2) The manufacturer must ensure that clinical evidence demonstrating that the device complies with the applicable provisions of the essential principles is documented in writing.

C CONFORMITY ASSESSMENT PROCEDURES FOR EACH CLASS OF MEDICAL DEVICE

1 OVERVIEW

Depending on the classification of a device, there are different conformity assessment procedures a manufacturer may use to demonstrate compliance with the Essential Principles. The table below summarises the most commonly used conformity assessment procedures for each medical device classification.

The table also indicates the relevant clause (in Section B of this guideline) that describes which South African Declaration of Conformity is appropriate for each conformity assessment procedure.

Class of Medical Device	Most commonly used conformity assessment procedures	Declaration of Conformity reference
Class A	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment)	Part 6, clause 6.6
Class A (measuring) and Class B (non-sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment) + Part 5 (Product Quality Assurance Procedures)	Part 6, clause 6.6
Class A (sterile) and Class B (sterile)	Part 6 (Declaration of Conformity Procedures Not Requiring Assessment) + Part 4 (Production Quality Assurance Procedures)	Part 6, clause 6.6
Class C	Part 1 excluding Clause 1.6 (Full Quality Assurance Procedures)	Part 1 clause 1.8
Class D	Part 1 (Full Quality Assurance Procedures) + Clause 1.6 (Examination of Design)	Part 1 clause 1.8
Systems or Procedure Packs	Part 7 (Procedures for Medical Devices Used for a Special Purpose)	Part 7, clause 7.2

The following conformity assessment procedures are rarely used as they are generally more expensive for manufacturers, but are options that can be considered:

Part 2 (Type Examination) for specific models of Class C, Class D, (including Active Implantable devices), in conjunction with Part 1 or Part 3 or Part 4 or Part 5.

Part 3 (Verification Procedures) for non-sterile Class A measuring and Class B devices or, when used in conjunction with Part 2, for non-sterile Class C and Class D devices.

More information on all these options is provided in the next table.

2 SUMMARY

[The "Parts" are as noted in Section B of this Guideline]

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 1, Full quality assurance procedure Encompasses design, production, packaging, labelling, and final inspection of a medical device	Manufacturer must implement a full quality management system (that is, all clauses of ISO 13485 including clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by a Conformity Assessment Body. The manufacturer's technical documentation for the medical devices, including clinical evidence is also assessed.	All Please note: for Class D - Clause 1.6 must also be applied	This conformity assessment procedure can be applied to all devices that they manufacturer This means that new devices that are Class A measuring and/or sterile, Class B or Class C that fit into the scope of the certificate should not require additional assessment(s) by the Conformity Assessment Body. Resources required establishing and maintaining appropriate procedures. The quality management system must be maintained. Periodic surveillance audits will be performed by the Conformity Assessment Body or other Notified Body.
Part 1, Clause 1.6, Examination of Design Involves an examination of the design dossier for medical devices to which the manufacturer has applied a Part 1 conformity assessment procedure	The technical documentation for the Class D (also referred to as a design dossier) must be submitted for examination to assess the compliance of the device with the Essential Principles.	Class D	The overhead cost of the assessment may be high. This must be done in conjunction with Part 1 assessment of the quality management system; by the Conformity Assessment Body.
Part 2, Type examination Involves an examination of a representative sample of a medical device	Testing can be conducted by the Conformity Assessment Body, OR the Conformity Assessment Body can conduct tests on the device at the manufacturer's site and supervise or review the testing, OR	Class C, Class D	Only applies to a specific medical device model. The overhead cost of the assessment may be high. The production of subsequent devices still require conformity assessment under: Part 4 for sterile devices. Part 3, Part 4, or Part 5 for other devices.

Part	Requirements	Applicable classifications	Considerations for manufacturer
	the Conformity Assessment Body will subcontract the testing to an accredited test laboratory (either in South Africa or outside of South African borders).		
Part 3, Verification Procedures Involves an examination (including testing) of the medical device(s) prior to release for supply	The Conformity Assessment Body will need to assess production records for each device (either on a statistical basis or a 100 % sampling rate) and authorise release of the product or batch of products for supply.	Class A (measuring), Class B, Class C & Class D. Please note: can not be used for sterile devices	May be appropriate if the manufacturer does not have a quality management system. Only applies to the production processes for a specific medical device. Only applies to a particular production batch or particular production units. Certification must be repeated prior to every new batch or device being released onto the market. As many test procedures need to be designed, established and qualified before testing can begin, the overhead cost of the assessment may be high. The design of Class A (measuring) and Class B devices still requires conformity assessment under Part 6. The design of Class C and Class D devices still requires conformity assessment under Part 2.
Part 4, Production quality assurance A quality management system encompassing the production and final inspection of a medical device	Manufacturer must implement a quality management system (i.e. all clauses of ISO 13485 excluding clause 7.3 but including clause 7.5.2) and arrange for the quality management system to be audited by the Conformity Assessment Body The Conformity Assessment Body also reviews a sample of the manufacturer's technical documentation for the devices.	Class A - measuring and/or sterile, Class B, Class C & Class D.	Assessment can cover a wide range of devices—not limited to a specific device. For Class A - measuring and/or sterile and Class B devices this only covers production—the design of each device still requires Part 6 conformity assessment. For Class C & Class D devices this only covers production—the design of each device still requires conformity assessment under Part 2. May be resource intensive to initially establish appropriate procedures. The quality management system must be maintained

Part	Requirements	Applicable classifications	Considerations for manufacturer
			Periodic surveillance audits will be performed by the Conformity Assessment Body
Part 5, Product quality management system A system encompassing the final inspection and testing of a medical device	Manufacturer must implement a quality management system (that is, ISO 13485 excluding clauses 7.3 and 7.5.2) and arrange for the quality management system to be audited by the Conformity Assessment Body. The Conformity Assessment Body also reviews a sample of the manufacturer's technical documentation for the devices.	Class A - measuring, Class B, Class C Please note: cannot be used for sterile devices	Assessment can cover a wide range of devices—not limited to a specific device. For Class A - measuring and Class B devices this only covers production—the design of each device still requires Part 6 conformity assessment. For Class C devices this only covers production—the design of each device still requires conformity assessment under Part 2. May be resource intensive to initially establish appropriate procedures. The quality management system must be maintained Periodic surveillance audits will be performed by the Conformity Assessment Body
Part 6, Declaration of Conformity (not requiring assessment) Preparing technical documentation for a medical device and establish a post-market monitoring system	Manufacturer ensures that the device(s) comply with the Essential Principles and prepares documentation that demonstrates conformity.	Class A, Class A - measuring and/or sterile, Class B	For Class A non-measuring and non-sterile devices the evidence (Declaration of Conformity) is not required to be submitted to the Council but MUST be available upon request. For Class A (measuring and sterile) and Class B devices, conformity assessment under Part 3, Part 4 (sterile devices) or Part 5 is also required.
Part 7, Conformity Assessment Procedures for devices used for a Special Purpose	Applies to Groups, systems and procedure packs	All Please note: sterile Groups, systems and procedure packs also require Part 4 certification	For Groups, systems and procedure packs, see Part 7. Systems and procedures packs.

Part	Requirements	Applicable classifications	Considerations for manufacturer
Part 8, Clinical Evaluation procedures	The conformity assessment procedures the manufacturer must follow for obtaining and evaluating clinical data.	All	See The Essential Principles, Essential Principle 14-Clinical evidence

3 CLASS D MEDICAL DEVICES

3.1 Subject to 3.2, the conformity assessment procedures that must be applied to a Class D medical device are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

(b) the type examination procedures and:

(i) the verification procedures; or

(ii) the production quality assurance procedures.

3.2 If the device is intended by the manufacturer to be supplied in a sterile state, the conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

(b) the type examination procedures and the production quality assurance procedures.

4 CLASS D IVD MEDICAL DEVICES

The conformity assessment procedures that must be applied to a Class D IVD medical device are, as the manufacturer prefers:

(a) the full quality assurance procedures; or

(b) the type examination procedures and the production quality assurance procedures.

5 CLASS C MEDICAL DEVICES

5.1 Subject to 5.2, the minimum conformity assessment procedures that must be applied to a Class C medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the type examination procedures and:

(i) the verification procedures; or

(ii) the production quality assurance procedures; or

(iii) the product quality assurance procedures.

5.2 If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the type examination procedures and the production quality assurance procedures.

6 CLASS C IVD MEDICAL DEVICES

The minimum conformity assessment procedures that must be applied to a Class C IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the type examination procedures and the production quality assurance procedures.

7 CLASS B MEDICAL DEVICES

7.1 Subject to 7.2, the minimum conformity assessment procedures that must be applied to a Class B medical device (other than a medical device used for a special purpose) are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures and:

(i) the verification procedures (other than clause 3.5 of Section B); or

(ii) the production quality assurance procedures (other than clause 4.7 of Section B); or

(iii) the product quality assurance procedures (other than clause 5.7 of Section B).

7.2 If the device is intended by the manufacturer to be supplied in a sterile state, the minimum conformity assessment procedures that must be applied to the device are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the production quality assurance procedures (other than clause 4.7 of Section B) and the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures.

8 CLASS B IVD MEDICAL DEVICES

The minimum conformity assessment procedures that must be applied to a Class B IVD medical device, other than a device to be used for a special purpose, are, as the manufacturer prefers:

(a) the full quality assurance procedures (other than clause 1.6 of Section B); or

(b) the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures and the production quality assurance procedures, other than clause 4.7 of Section B.

9 CLASS A MEDICAL DEVICES

9.1 Subject to 9.2 and 9.3, the minimum conformity assessment procedures that must be applied to a Class A medical device (other than a medical device used for a special purpose) are the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures.

9.2 If the device is intended by the manufacturer to be supplied in a sterile state, and the manufacturer applies the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures to the device, the production quality assurance procedures (other than clause 4.7 of Section B) must also be applied to the device.

9.3 If the device has a measuring function, and the manufacturer applies the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures, one of the following sets of procedures, as the manufacturer prefers, must also be applied to the device:

(a) the verification procedures (other than clause 3.5 of Section B);

(b) the production quality assurance procedures (other than clause 4.7 of Section B);

(c) the product quality assurance procedures (other than clause 5.7 of Section B).

10 CLASS A IVD MEDICAL DEVICES

The minimum conformity assessment procedures that must be applied to a Class A IVD medical device, other than a device to be used for a special purpose, are the declaration of conformity (not requiring assessment by Conformity Assessment Body) procedures.

11 MEDICAL DEVICES USED FOR A SPECIAL PURPOSE

11.1 This applies to the following kinds of medical devices (***medical devices used for a special purpose***):

(a) a system or procedure pack;

(b) a system or procedure pack that contains at least 1 medical device, that is not an IVD medical device, and at least 1 IVD medical device.

Note: A system or procedure pack is treated as a single medical device.

If paragraph 11.1(b) does not apply to a system or procedure pack, the conformity assessment procedures that must be applied to the system or procedure pack are the procedures that apply to the relevant classification.

For the system or procedure pack: the conformity assessment procedures that must be applied to the system or procedure pack are the procedures for medical devices used for a special purpose.

Note for 11.1(b): A system or procedure pack that contains both a medical device (that is not an IVD medical device) and an IVD medical device is treated as a single medical device.

11.2 The conformity assessment procedures that must be applied to a medical device used for a special purpose are the procedures for medical devices used for a special purpose.

11.3 This applies to a system or procedure pack:

(a) that contains only one or more of the following:

(i) a medical device, or devices, to which the relevant conformity assessment procedures have been applied;

(ii) a medicine or medicines, a biological or biologicals, or other therapeutic goods, that are entered on the Register;

(iii) any other item or items that are not therapeutic goods when in the package; and

(b) that has been put together in accordance with the intended purpose of each medical device and the approved indications for use of each medicine, biological and other therapeutic goods; and

(c) the contents of which are compatible, having regard to the intended purpose of each medical device, the approved indications for use of each medicine, biological or other therapeutic goods, and the intended purpose of the system or procedure pack.

11.4 If a system or procedure pack is intended by the manufacturer to be supplied in a sterile state, the production quality assurance procedures (other than clause 4.7 of Section B) must also be applied to the system or procedure pack in relation to the aspects of the manufacturing process that relate to ensuring that the system or procedure pack is supplied and maintained in a sterile state.

12 RECORDS TO BE PROVIDED IN ENGLISH

All records (including correspondence) provided by the manufacturer of a medical device in relation to the application of the conformity assessment procedures to the device must be in at least English.

D CONFORMITY ASSESSMENT CERTIFICATES

1 ISSUE AND SUSPENSION OF CONFORMITY ASSESSMENT CERTIFICATES

The Conformity Assessment Body will notify Council and SANAS in the event a Conformity Assessment Certificate is issued.

The Conformity Assessment Body will notify Council and SANAS in the event a Conformity Assessment Certificate is suspended, whereby Council will suspend the registration of the medical device or IVD from the register, for a period of 90 days.

An application by a manufacturer, distributor or wholesaler to a Conformity Assessment Body to revoke the suspension of a conformity assessment certificate will be forwarded by the Conformity Assessment Body to Council. The Conformity Assessment Body will provide evidence to support the revocation or denial thereof to Council. Council may require the manufacturer, distributor or wholesaler to provide additional information to cancel the suspension of the medical device or IVD from the register or remove the medical device or IVD from the register.

During suspension – the medical device or IVD may not be sold in South Africa.

2 TRANSFER OF CONFORMITY ASSESSMENT CERTIFICATES

This applies in relation to a manufacturer of a medical device and IVD in respect of whom a conformity assessment certificate is issued.

2.1 Death, bankruptcy or winding up of manufacturer

(1) If the manufacturer dies, the manufacturer's legal personal representative:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Conformity Assessment Body and Council, in writing, of the death not later than 1 month after it occurred.

(2) If the manufacturer becomes bankrupt, the trustee in bankruptcy of the manufacturer's estate:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Conformity Assessment Body and Council in writing, of the manufacturer's bankruptcy not later than 1 month after it occurred.

(3) If the manufacturer is a body corporate that is wound up, the liquidator of the body corporate:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must notify the Conformity Assessment Body and Council, in writing, of the winding up of the body corporate not later than 1 month after it occurred.

2.2 Disposal of business or amalgamation with another manufacturer

(1) This regulation applies if the name of the manufacturer is changed in any of the following circumstances:

(a) the manufacturer agrees to dispose of a business concerned with the manufacture of the medical device, and it is agreed that the disposal is to include a transfer of the conformity assessment certificate issued in respect of the manufacturer and the medical device;

2.2 Disposal of business or amalgamation with another manufacturer - continued

(b) in the case of a manufacturer that is a body corporate—the manufacturer amalgamates with another body corporate under a name that is different from the name of the manufacturer on the conformity assessment certificate.

(2) The person to whom the business is disposed of, or the body corporate with whom the manufacturer amalgamates:

(a) is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(b) must, not later than 1 month after the disposal or amalgamation, apply to the Conformity Assessment Body and Council, in writing, for the name of the manufacturer to be changed on the conformity assessment certificate.

2.3 Change of name of manufacturer

If the name of the manufacturer is changed:

(1) the manufacturer, as renamed, is taken to be the person in respect of whom the conformity assessment certificate is issued; and

(2) the manufacturer must, not later than 1 month after the name is changed, notify the Conformity Assessment Body and Council, in writing, of the new name and the circumstances in which the change occurred.

2.4 Effect of conformity assessment certificate after transfer, etc.

If a conformity assessment certificate is taken to be issued in respect of a person because of the operation of 2.1; 2.2 or 2.3:

(1) the certificate has effect as if it had actually been issued in respect of that person; and

(2) the medical devices to which the certificate relates may continue to be manufactured while the certificate is in effect.

2.5 Notification to Conformity Assessment Body and Council of events

(1) If a person is required to notify the Conformity Assessment Body and Council of an event under this guideline, the person must send to the Conformity Assessment Body and Council sufficient documentary evidence to establish the matter asserted in the notification.

(2) If, at any time, the Conformity Assessment Body or Council becomes aware that he or she has not been notified of an event as required, the Conformity Assessment Body may suspend or revoke the conformity assessment certificate to which the event relates.

2.6 Notification of change of name or suspension or revocation of conformity assessment certificate

(1) If the Conformity Assessment Body:

(a) changes the name of a manufacturer on a conformity assessment certificate; or

(b) suspends or revokes a conformity assessment certificate issued in respect of a manufacturer;

the Conformity Assessment Body must, as soon as practicable after changing the name or suspending or revoking the conformity assessment certificate:

(i) notify the Council and the manufacturer that the name has been changed or the conformity assessment certificate has been suspended or revoked; and

(ii) ask the manufacturer to return to the Conformity Assessment Body the conformity assessment certificate that was given before the change of name or suspension or revocation.

(2) If a manufacturer receives a notice under clause 2.6(1), the manufacturer must return to the Conformity Assessment Body, as soon as practicable after receiving the notice, the conformity assessment certificate that was given before the change of name or suspension or revocation.

UPDATE HISTORY

Date	Reason for update	Version & publication
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