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National Agency for Food & Drug Administration & Control (NAFDAC)

Vaccines, Biologics and Medical Devices Registration & Regulatory Affairs Directorate

NAFDAC Guidelines for Conformity Assessment of Non-In Vitro Diagnostics (nIVDs) Medical Devices

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1.0 Acknowledgement

The Agency acknowledges the adoption of IMDRF document No. **GHTF/SG1/N046:2008** and the technical support of the International Medical Device Regulators Forum (IMDRF) in the development of these guidelines.

2.0 Rationale, Purpose, and Scope

2.1 Rationale

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

Conformity assessment is primarily the responsibility of the medical device manufacturer. However, it is undertaken in the context of the regulatory requirements established in the jurisdiction where the device is sold, and both the process and conclusions may be subject to further review by the Agency.

2.2 Purpose

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 by the manufacturer.
- The conformity assessment elements that apply to each class of device such that the regulatory demands increase with the hazard presented by a particular medical device;
- The process by which the Agency would 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'.

2.3 Scope

This document applies to all products that fall within the definition of the term 'medical device', other than IVD medical devices, for which separate classification and conformity assessment documents exist.

3.0 References[1]

GHTF/SG1/N011:2008 *Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED).*

GHTF/SG1/N044:2008 *Role of Standards in the Assessment of Medical Devices.*

GHTF/SG1/N55:2009 *Definition of the Terms Manufacturer, Authorised representative, Distributor and Importer.*

GHTF/SG1/N065:2010 *Registration of Manufacturers and other Parties and Listing of Medical Devices*.

GHTF/SG1/N068:2012 *Essential Principles of Safety and Performance of Medical Devices.*

GHTF/SG1/N070:2011 *Label and Instructions for Use for Medical Devices.*

GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*

GHTF/SG1/N077:2012 *Principles of Medical Devices Classification.*

GHTF/SG2/N054R8:2006 *Medical Devices Post Market Surveillance: Global Guidance for Adverse Event Reporting for Medical Devices.*

GHTF/SG3/N99-10:2004 (Edition 2) *Quality Management Systems - Process Validation Guidance*

GHTF/SG3/N15R8:2005 *Implementation of Risk Management Principles and Activities Within a Quality Management System*

GHTF/SG3/N17:2008 *Quality Management System - Medical Devices - Guidance on the Control of Products and Services Obtained from Suppliers*

GHTF/SG3/N18:2010 *Quality Management System - Medical Devices - Guidance on corrective action and preventive action and related QMS processes*

GHTF/SG4/N028R4:2008 *Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers – Part1: General Requirements.*

GHTF/SG5/N1R8:2007 *Clinical Evidence – Key Definitions and Concepts*

GHTF/SG5/N2R8:2007 *Clinical Evaluation*

GHTF/SG5/N3:2010 *Clinical Investigations*

GHTF/SG5/N4:2010 *Post Market Clinical Follow-Up Studies*

[1] The listed documents are subject to periodic review and may be superseded by later versions. The reader is encouraged to refer to the GHTF website to confirm whether the referenced documents remain current.

4.0 Definitions

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 based on which an audit is conducted.

Audit Evidence: Records, statements of fact, or other information, that 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: The systematic examination of evidence generated and procedures undertaken by the manufacturer, under requirements established by the Regulatory Authority, to determine that a medical device is safe and performs as intended by the manufacturer and, therefore, conforms to the *Essential Principles of Safety and Performance for Medical Devices (SG1/N041)*.

Recognized Standards: Standards deemed to offer the presumption of conformity to specific essential principles of safety and performance.

Medical Device: Refers to Non-In Vitro Diagnostic Medical Device as defined in the GHTF/SG1/N071:2012 *Definition of the Terms 'Medical Device' and 'In Vitro Diagnostic (IVD) Medical Device'*

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*.

Use error: Act, or omission of an act, that has a different result to that intended by the manufacturer or expected by the operator. Use error includes slips, lapses, mistakes, and reasonably foreseeable misuse.

5.0 Conformity Assessment Elements

Medical device regulations should specify the way the manufacturer demonstrates to the Agency that its medical devices comply with the legislation. The necessary conformity assessment elements are:

i. A quality management system (QMS),

ii. A system for post-market surveillance,

iii. Technical documentation,

iv. A declaration of conformity, and

v. The recognition of manufacturers and registration of their medical devices by the Agency.

All five elements are required for each of the device classes but there is flexibility in the manner of their application to a particular device class e.g. whether or not the technical documentation is subject to premarket review by the Agency. Where there are alternatives within a conformity assessment element, the manufacturer may choose the one that it uses.

Where a substantial change to either the device or to the manufacturer's QMS is planned that could affect one of the conformity assessment elements, the Agency should be notified for assessment by the Agency prior to implementation.

The conformity assessment elements that appear in Sections 5.1 to 5.5 describe the tasks of the manufacturer and, where appropriate, the responsibilities of the Agency. Specific guidance on how these conformity assessment elements should be applied to a particular class of device is provided in the four tables in Section 6.2.

The requirements for a QMS that is accepted by the Agency for regulatory purposes and based on international recognised standards[2], combined with the other four conformity assessment elements are intended to ensure that medical devices will be safe and perform as intended by the manufacturer.

[2] See definition in Section 4.0.

5.1 Quality Management System (QMS)

The manufacturer should implement, document, and maintain a QMS that ensures the medical devices it designs, manufactures and supplies to the market are safe, perform as intended, and comply with the relevant provisions of the regulations. The scope and complexity of the QMS are influenced by the range of different medical devices that are under QMS control, the processes employed, the size and structure of the organization, and the specific regulatory requirements.

Processes required by the QMS but carried out on the manufacturer's behalf by third parties remain the responsibility of the manufacturer and are subject to control under the manufacturer's QMS. As part of the Agency's conformity assessment process, it would assess the adequacy of this control.

Conformity assessment of the manufacturer's QMS is influenced by the class of the medical device, as follows:

i. Manufacturers of **Class A** devices should implement and maintain the basic elements of a QMS but have the option of excluding design and development controls from it. The QMS for manufacturers of **Class A** devices would be subject to premarket on-site audit by the Agency.

ii. Manufacturers of **Class B** devices should implement and maintain an effective QMS but may have the option of excluding design and development controls from it.

iii. Manufacturers of **Class C and D** devices should implement and maintain an effective QMS that includes design and development controls and complies with the Agency's guidance documents.

For **Class B, C, and D** devices, the Agency needs to have confidence that the manufacturer has an appropriate and effective QMS in place, suitable for the range of different medical devices that are under QMS control. To achieve this, the Agency would undertake on-site audits of the manufacturer's facility to confirm that the QMS meets the requirements of the relevant medical device regulations.

Complete quality management systems are preferred because they implement a full cycle of design and development controls to ensure that medical devices comply with the relevant Essential Principles of Safety and Performance. For products that are in existence at the time of establishment of a QMS, evidence of design control and the resulting outputs would be difficult for the manufacturer to demonstrate retrospectively. In these circumstances, the manufacturer may request the Agency, to conduct a type examination to verify conformity with the relevant Essential Principles and to establish a baseline for entry into the design and development cycle. It is expected that for future design changes to this product, originally assessed for conformity by type examination, or for the introduction of a new product, the manufacturer would introduce the full design and development controls of the QMS.

If the manufacturer chooses to use type examination by the Agency, this will be indicated in the technical documentation and ToC

The use of type examination does not replace the need to establish and maintain a QMS that covers all manufacturing activities.

5.2 System for post-market surveillance

Before placing the product on the market, the manufacturer will establish, as part of its QMS, a process to assess the continued conformity of the device to the *Essential Principles of Safety and Performance* through the post-marketing phase. This process will include complaint handling, post-market vigilance reporting, and any subsequent corrective & preventive actions[3].

The Agency would confirm that such a process is in place, usually at the time of the QMS audit[4].

Furthermore, the Agency may require manufacturers to perform a specific post-marketing study of a particular type of device and report the outcome to NAFDAC.

The Agency would monitor any post-marketing study and consider whether any additional regulatory action is required after analyzing the outcome.

5.3 Technical documentation

Manufacturers of all classes of devices are expected to demonstrate the conformity of the device to the *Essential Principles of Safety and Performance of Medical Devices* through the preparation and holding of technical documentation that shows how each medical device was developed, designed, and manufactured together with the descriptions and explanations necessary to understand the manufacturer's determination concerning such conformity. This technical documentation is updated as necessary to reflect the current status, specification, and configuration of the device.

As part of its task to demonstrate the conformity of a device to the medical device regulations, the manufacturer should create the *Technical Documentation for demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices* (ToC) using the **Guidelines for Compilation of a Product Dossier for Registration of Non-In Vitro Diagnostic (nIVD ToC)** to provide evidence to the Agency that the subject medical device conforms with the essential principles of safety and performance, labelling, risk analysis, and other regulatory requirements. The ToC reflects the status of the medical device at a particular moment in time (e.g. at the moment of premarket submission or when requested by the Agency for post-marketing purposes) and is prepared to meet regulatory requirements. The extent of evidence in that ToC is likely to increase with the class of the medical device, its complexity, and the extent to which it incorporates new technology.

The submitted ToC, should incorporate an attestation that the contents are truthful and

accurate, and indicate the name, position, and signature of the responsible person who has been authorized to submit it on the manufacturer's behalf.

[3] See GHTF/SG2 guidance documents.

[4] Further details are provided in the GHTF guidance documents issued by Study Groups 3 and 4.

The Agency would determine the adequacy of the documented evidence in support of the manufacturer's attestation of conformity to the essential principles of safety and performance, and other regulatory requirements, through a review of the ToC. The depth and timing of the review will be influenced by the class of the medical device, its complexity, and the extent to which it incorporates new technology.

5.4 Declaration of Conformity

One element of a global regulatory model for medical devices is that the manufacturer attests that its medical device complies fully with all regulatory requirements and draws up a written 'Declaration of Conformity'.

As a minimum, this declaration should contain the following:

- An attestation that each device that is subject to the declaration complies with the applicable *Essential Principles for Safety and Performance* and the applicable requirements of *Label and Instructions for Use for Medical Devices*,
- Information sufficient to identify the device/s to which the Declaration of Conformity applies.
- The Global Medical Device Nomenclature (GMDN) code for the device[5].
- The classification of the device/s after following the guidance found in *Principles of Medical Devices Classification*.
- The date on which the Declaration of Conformity is issued.
- The name and address of the device manufacturer.
- The name, position, and signature of the responsible person who has been authorized to complete the Declaration of Conformity on the manufacturer's behalf.

The Agency may review and confirm the adequacy of the Declaration of Conformity and, if required, examine the supporting documents or other evidence.

[5] www.gmdnagency.com

5.5 Recognition of manufacturers and registration of their medical devices by NAFDAC

The collection and retention of information on manufacturers, authorized representatives, importers, and distributors and the medical devices supplied to the market by those parties are used as part of the fundamental elements of regulatory control of medical devices by NAFDAC.

6.0 Harmonized Conformity Assessment System

6.1 The relationship between conformity assessment and device classification

The Agency recommends that each medical device be allocated to one of four groups or 'classes', using a set of rules derived from the potential of a medical device to cause harm to a patient or user (i.e. the hazard it presents).

Class A devices offer the lowest hazard, Class B devices present low to moderate hazard, Class C devices have moderate to high hazard, and Class D has the highest hazard ranking. The level of regulatory oversight, the evidence requirements that the device meets the *Essential Principles for Safety and Performance*, and the conformity assessment elements, become more robust and demanding as the classification of the device increases from A to D.

This principle is illustrated in Section 6.2 below. It identifies available conformity assessment elements and proposes a combination of those elements that may be applied to different classes of medical devices. Where there are alternatives within a conformity assessment element, e.g. the QMS for a Class A device may be either a complete QMS or one without design and development control, the manufacturer may choose the one that it believes to be most suitable.

6.2 Conformity assessment system

The four tables below summarise conformity assessment elements that apply to Class A, B, C, and D devices.

CLASS A DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Section
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS **or** a QMS without design and development controls.	Regulatory audit required.	5.1
	Post-market Surveillance	Establish and maintain an adverse event reporting procedure according to GHTF SG2 guidance.	May audit post-market to investigate specific safety or regulatory concerns.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Establish and keep up to date, technical documentation, and prepare and submit ToC only at the request of the Agency	Premarket submission of ToC is normally not requested.	5.3
	Declaration of Conformity	Prepare, sign, and maintain.	Submission is normally not requested.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

CLASS B DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System	Establish and maintain a complete QMS **or** a QMS without design and development controls.	Have confidence that a current and appropriate QMS is in place and conduct a QMS audit before marketing authorization.	5.1
	Post-market Surveillance	Establish and maintain an adverse event reporting procedure according to NAFDAC guidelines.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Establish and keep up-to-date, technical documentation, and prepare and submit ToC only at the request of the Agency.	Not normally reviewed premarket. If submission is requested, receive and conduct a premarket review of the ToC sufficient to determine conformity to Essential Principles.	5.3
	Declaration of Conformity	Prepare, sign, and make available for review.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

CLASS C DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS.	Have confidence that a current and appropriate QMS is in place and conduct a QMS audit before marketing authorization.	5.1
	Post-market Surveillance	Establish and maintain an adverse event reporting procedure according to NAFDAC guidelines.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Establish and keep up-to-date, technical documentation, and prepare and submit a ToC for review.	Undertake a review of the ToC sufficient to determine conformity to Essential Principles, prior to the device being placed on the market.	5.3
	Declaration of Conformity	Prepare, sign, and submit.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

CLASS D DEVICE

	Conformity Assessment Element	Manufacturer Responsibility	NAFDAC Responsibility	Sub-Clause
Conformity assessment of the QMS	Quality Management System	Establish and maintain a full QMS.	Have confidence that a current and appropriate QMS is in place and conduct a QMS audit before marketing authorization.	5.1
	Post-market Surveillance	Establish and maintain an adverse event reporting procedure according to NAFDAC guidelines.	Be satisfied that a current and appropriate adverse event reporting procedure is in place as part of the QMS.	5.2
Conformity assessment of device safety & performance	Technical Documentation	Establish and keep up-to-date, technical documentation, and prepare and submit a ToC for review.	Undertake an in-depth review of the ToC to determine conformity to Essential Principles, before the device is placed on the market.	5.3
	Declaration of Conformity	Prepare, sign, and submit.	Review and verify compliance with requirements.	5.4
Registration	Registration of manufacturers and their devices	Perform according to regulatory requirements.	Maintain and verify as appropriate.	5.5

6.3 Conformity Assessment Considerations

There are situations when characteristics of the device and/or its manufacturer may cause the Agency, by exception, to modify requirements relating to its conformity assessment. For example, the Agency may exempt the manufacturer from making a complete premarket submission and/or require a less rigorous audit than would apply normally to a device of that class when:

- The device incorporates well-established technology that is present in the market already;
- The Agency is familiar with the manufacturer's capabilities and its products;
- The device is an updated version of a compliant device from the same manufacturer that contains little substantive change;
- The Agency has particular experience with a comparable device;
- Internationally recognised standards[6] are available to cover the main aspects of the device and have been used by the manufacturer.

Similarly, the Agency may require more detailed premarket submission and/or require a more rigorous audit and/or the provision of more clinical evidence than would apply normally to a device of that class when:

- The device incorporates innovative technology;
- An existing compliant device is being used for a new intended use;
- The device type is new to the manufacturer;
- The device type tends to be associated with an excessive number of adverse events, including use errors[7];
- The device incorporates innovative or potentially hazardous materials;
- The device type raises specific public health concerns.

It should be emphasized that there must be a fully justified and documented case before the Agency would modify in any way the relationship between the device class and the associated conformity assessment element. Where there is justification for variation to the conformity assessment elements normally applicable to a particular device class, a statement in this regard should be included in the ToC.

[6] See definition in Section 4.0.

[7] See GHTF/SG2 guidance documents.