SAHPRA
South African
Health Products
Regulatory Authority

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COMMUNICATION TO STAKEHOLDERS

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ISO 13485 Certificate as a prerequisite for the approval of a Medical Device Establishment Licence

INTRODUCTION

The international standard ISO 13485 (ISO 13485:2016 Medical Devices - Quality Management Systems – Requirements for regulatory purposes) for a quality management system (QMS) is recognised globally to address minimum regulatory requirements for medical devices and in vitro diagnostics (IVDs). The standard outlines the requirements for manufacturers and suppliers of medical device and IVDs, and it establishes a minimum quality assurance framework to ensure medical devices and IVDs are managed appropriately with the intention to provide medical device and IVDs which are safe and perform as intended by the manufacturer.

While different jurisdictions may vary in specific regulatory details, the ISO 13485 standard provides a framework for manufacturers and distributors involved in one or more stages of the life cycle of a medical device and IVDs, including the design and development, production, storage and distribution, installation, servicing, final decommissioning and disposal of a medical device, and provision of associated activities (e.g. technical support) to address the QMS requirements set by the majority of national regulatory authorities (NRAs). The South African Health Products Regulatory Authority (SAHPRA) established a similar approach to address the management of quality assurance of medical device and IVDs, in South Africa.

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On 24 February 2017, the Registrar of the Medicines Control Council (MCC) and the Department of Health published a notice in the Government Gazette[1] of the resolution of the MCC, whereby all manufacturers, distributors and wholesalers (as referred to in Section 22C (1)(b) of the Medicines and Related Substances Act[2]), were required to obtain a medical device licence within the published timeframe to operate within South Africa as contemplated in the Medicines and Related Substances Act, read together with Regulation 27(2) of the Regulations relating to Medical Devices and IVDs. [3]

Furthermore, the requirements according to Regulation 5(1) of the Regulations relating to Medical Devices and IVDs[4], were noted in the licensing call-up notice of 24 February 2017[5]. This included, as per Regulation 5(1) (c)(iii), the requirement for the applicant for a licence (as referred to in Section 22C (1)(b) of the Medicines and Related Substances Act) to provide "*acceptable documentary proof of certification to a Quality Management System for Medical Devices and IVDs, as determined by the Council*".

In terms of Regulation 6 of the Regulations relating to Medical Devices and IVDs, the validity of a licence issued in terms of Regulation 5 is valid for five (5) years from date of issue, and an application for a renewal of a licence must "*contain at least the information or documentation referred to in regulation 5(1) (c), as the case may be*" with the prescribed fee and within the determined timeline.

[1] Medicine and Related Substances Act, 1965 (Act 101 of 1965), Department of Health Notice No. 157, Government Gazette No 40637, 24 February 2017.
[2] Medicines and Related Substances Act 101 of 1965, as amended
[3] Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016.
[4] Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016.
[5] Medicine and Related Substances Act, 1965 (Act 101 of 1965), Department of Health Notice No. 157, Government Gazette No 40637, 24 February 2017.

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The purpose of this communication is to:

a) **outline the phased process (refer to annexure A) which SAHPRA has followed to date to verify ISO 13485 certificates, and**
b) **to provide stakeholders with clarity of the requirements and timelines for submission of information to the regulator.**

SAHPRA will continuously implement the phased approach to verify compliance (refer to Annexure A), by requesting each holder of a medical device establishment licence to submit documentary proof of QMS certification to the ISO 13485 standard (refer to Annexure B).

Phase 1.

The initial plan by the MCC and thereafter SAHPRA, was that presentation of documentary proof of certification to the *International Standard ISO 13485 Medical Devices – Quality managements systems – Requirements for regulatory purposes* (herein after referred to as "ISO 13485:2016" or latest published ISO standard version), by a holder of a licence issued in terms of Section 22C(1)(b) of the Medicines and Related Substances Act, would be required to be presented to SAHPRA five years after the issue of the first (initial) medical device establishment licence, and as per Regulation 6 of the Regulations relating to Medical Devices and IVDs[6], that is determined to be a licence renewal.

This plan was for the first cohort of holders of a medical device establishment licence (issued in 2017 and 2018), in terms of Section 22C (1)(b), to provide an ISO 13485:2016 certificate upon application for renewal for a medical device establishment licence.

On 17 January 2022, SAHPRA published a Communication to Stakeholders_*MD030: Medical Device Establishment Licence Renewal – ISO 13485:2016 Certificate Communication*, outlining the amendment to the timeline for the implementation of the ISO 13485:2016 certification requirement, from April 2022 to April 2025. This was due to the delay in accreditation of South African Conformity Assessment Bodies (CABs). The additional three (3) years (i.e. after the first 5-year period of grace)

[6] Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016.

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were also intended to allow Manufacturers and Distributors (Importers) of medical devices and IVDs sufficient time to have the relevant QMS certified by a CAB recognised by SAHPRA in order to meet the prevailing ISO 13485:2016 standard (or latest version thereof)

In September 2022, SAHPRA published a revised communication to stakeholders, *MD031 Medical Device Establishment Renewal Process_v2* regarding the process for renewal of a medical device establishment licence.

A list of required documents on STEP A: DOCUMENTS TO BE SUBMITTED, included the following:

iv. An ISO 13485:2016 QMS certificate in the name of the South African licensed medical device establishment and at the same address.

v. In case the organisation does not have a valid ISO 13485:2016 certificate, a declaration by the Authorised Representative that the organisation has implemented a quality management system aligned to the ISO 13485:2016 standard and that a certified copy of certification to ISO 13485:2016 standard will be submitted to the Authority once acquired on a date not later than 01 April 2025.

During this period of grace, from the first issue of a licence to 1 April 2025 (referred to as Phase 1) and to facilitate the uninterrupted supply of medical devices and IVDs in South Africa, SAHPRA relied on each holder of a medical device establishment licence to establish, implement and certify the relevant QMS, without providing evidence thereof to SAHPRA.

It is noted that SAHPRA and its predecessor, MCC, provided all stakeholders with sufficient time to implement a QMS relevant for medical device and IVDs to meet regulatory requirements and that communications regarding the process were comprehensive and timely. SAHPRA sensitised the medical device industry for the required certification to the ISO 13485:2016 standard as a prerequisite for the approval of a Section 22C (1)(b) licence and this included:

- information shared during industry engagements in 2023, 2024 and 2025;
- the requirements of the SAHPRA reference document; and
- responding to individual queries.

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Phase 2:

As per previous SAHPRA communications, and from **1 June 2025**, it is incumbent upon each holder of a medical device establishment licence, issued in terms of Section 22C of the Medicines and Related Substances Act, and is due for renewal, to meet the regulatory requirements and hold the relevant documentary proof of certification to the international standard *ISO 13485:2016 Medical Devices - Quality Management Systems – Requirements for regulatory purposes or latest version thereto.*

As per Section 22C (1) of the Act, and Regulation 5(1)(c) relating to Medical Devices and IVDs[7], The Authority (SAHPRA), requires a person who makes an application for a renewal of an existing licence to provide documentary proof of certification of the QMS to the international standard ISO 13485:2016 or latest version thereto to SAHPRA, which the Authority may deem necessary.

From **1 June 2025:**

- Manufacturers and Distributors (Importers) of medical devices and IVDs, who submit an application for a **renewal** of a medical device establishment licence are required to provide a valid ISO 13485:2016 certificate in the name of the South African licensed medical device establishment and at the same address, from a CAB recognised by SAHPRA; and;
- Manufacturers and Distributors (Importers) who submit an application for a **renewal** of a medical device establishment licence and are currently in the process of obtaining certification to ISO 13485:2016 are required to provide documentary proof of such agreement from a CAB recognised by SAHPRA, and once the certificate is acquired it must be submitted to SAHPRA for verification
- Verification of the ISO13485:2016 certificate will be done by SAHPRA at the time of review.

Documentary proof of certification of the QMS of the South African licensed medical device establishment, in the form of a valid ISO 13485 certificate and at the same address, to the international

[7] Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016.

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standard ISO 13485:2016 issued by a CAB recognised by SAHPRA, must be submitted to SAHPRA for purposes of verification in the following instances:

i) for an application for a **renewal** of a medical device establishment licence issued in terms of Section 22C of the Act, and

ii) as requested by SAHPRA (for the purpose of updating information, application reviews, investigations, and post-market vigilance activities, e.g. on receipt of a product complaint/patient injury, etc).

Phase 3:

With effect from **1 April 2026:**

- Manufacturers and Distributors (Importers) of medical devices and IVDs who is already in possession of a current and valid ISO 13485:2016, regardless of when the medical device establishment licence was issued, and is not required to apply for a new licence or renewal of a licence or amendment (including notifications) to a licence, will be requested to submit the ISO 13485:2016 certificate issued by a CAB recognised by SAHPRA for purposes of verification.
- Verification of the ISO13485:2016 certificate will be done by SAHPRA at time of submission.

Phase 4:

With effect from **1 June 2027**:

- Manufacturers and Distributors (Importers) who submits an amendment to a valid medical device establishment licence and amendment to the product list (notification), including those who made previous applications for a new medical device licence, will be required to submit a valid certification to ISO 13485:2016 or latest version thereto issued by a CAB recognised by SAHPRA, for purposes of verification at the time of application.
- Manufacturers and Distributors (Importers) who submit an application for an amendment or notification of a medical device establishment licence and are currently in the process of obtaining certification to ISO 13485:2016 or latest version thereto will be required to provide documentary proof of such agreement from a CAB recognised by SAHPRA, and once the certificate is acquired, it must be submitted to SAHPRA for verification.

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- Verification of the ISO 13485:2016 certificate or latest version thereto will be done by SAHPRA at the time of review.

Note: Phases 3 and 4 may run concurrently.

Phase 5:

With effect from **1 April 2028**,

- Manufacturers and Distributors (Importers) who submit an application for a new medical device establishment licence will be required to submit a valid certification to ISO 13485:2016 or latest version thereto issued by a CAB recognised by SAHPRA,
- Manufacturers and Distributors (Importers) who submit an application for a new medical device establishment licence and are currently in the process of obtaining certification to ISO 13485:2016 or latest version thereto will be required to provide documentary proof of such agreement from a CAB recognised by SAHPRA.

Documentary proof of certification to the international standard must be held by all Manufacturers and Distributors (Importers) of a medical device establishment licence, issued in terms of Section 22C of the Medicines and Related Substances Act, as amended, and Regulations 5 and 6 relating to Medical Devices and IVDs.[8]

Conclusion

In summary, all license holders under Section 22C of the Medicines and Related Substances Act must maintain documentary proof of accreditation (in the form of a valid ISO 13485 certificate or latest version thereto) of their Quality Management System (QMS) to the international standard ISO 13485:2016 or latest version thereto.

[8] Regulations relating to Medical Devices. Government Notice No. 1515, Government Gazette No. 40480 09 December 2016.

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The requirement for an ISO 13485 certificate is mandatory even in cases where the license holder is exempted from licensing requirements under Section 22C of the Medicines and Related Substances Act.

SAHPRA as an agile and responsive African health products regulator, has taken into consideration all the recommendations and concerns from the medical devices industry when developing this plan.

Boitumelo Semete-Makokotlela

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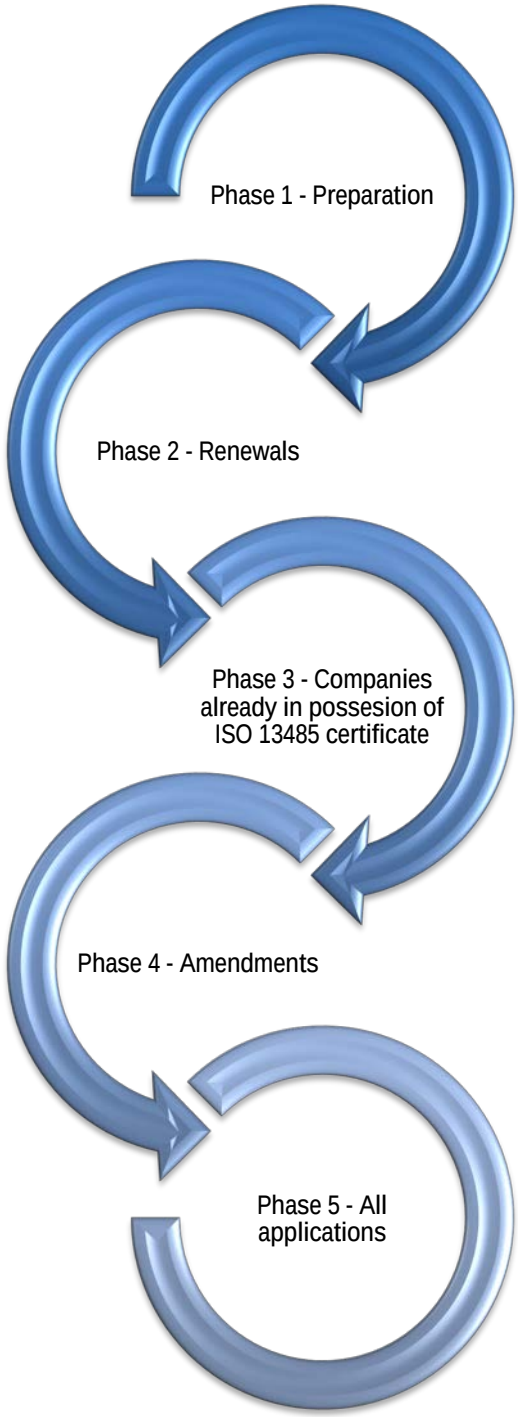
Annexure A: Implementation plan for the ISO 13485 requirement as a prerequisite for the approval of a Section 22C(1)b medical devices establishment licence



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Annexure B: Implementation timelines for the submission of ISO 13485 certification to SAHPRA

Phase	**Description**	**Effective Date for submission**
1.	Sensitisation of the industry to prepare for the implementation of the requirement.	No submission required to SAHPRA
2.	Renewal of medical device establishment licence	1 April 2025 - extended to 1 June 2025
3.	i) Holder of a medical device establishment licence which does not require amendment (of any nature) or renewal of such licence, but is in possession of an ISO 13485:2016 accreditation certificate which was not previously submitted to SAHPRA	1 April 2026
4	i) Amendment of medical device establishment licence where there is a change that affects the licence issued by the authority. ii) Amendment or update of the product list only (notification)	1 June 2027
5	i) All applications relating to a medical device establishment licence	1 April 2028