

# **SAMED COMPLIANCE OFFICERS CODE TOOLKIT**

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## 1. Overview

- The Medical Device Code for Ethical Marketing and Business Practice governs interactions between suppliers and their customers, namely healthcare providers and professionals. It fosters trust in the medtech industry by creating a framework for ethical activity that protects the reputation of industry stakeholders.
- The Code is an instrument for self-regulation of the medical technology industry and SAMED is the custodian of the Code. Its key principle is that signatories to the Code will not offer inappropriate inducements to healthcare providers and healthcare professionals in order to sell or lease their products.
- The *raison d'être* for the Medical Device Code of Ethical Marketing & Business Practice (the Code) is to ensure that all personnel that interact with Health Care Professionals and Organisations (HCPs/HCOs) do so in an ethical manner which ensures that decisions are made in the best interests of the patient and to eliminate any undue inducements regarding the use of products.
- It is a mandatory requirement that all 'customer facing' staff members of companies (or individuals) that are a SAMED member / signatory to the Code, are certified in respect of their understanding thereof every three years.
- It is incumbent upon company Compliance Officers to ensure that staff are compliant in accordance with the certification process.

## 2. Process for Compliance Officers to get registered on the Medical Practice Consulting (MPC) Platform

- SAMED has access to the on-line code certification system which allows it to monitor both the compliance of individuals as well as to ensure that the relevant Compliance Officers have verified such compliance.
- This process is undertaken in accordance with a three-year cycle verification period. The process provides assurance to all SAMED's stakeholders (Members, Member Customers, HCPs, HCOs, Regulatory Authorities and others) that a standard of compliance is adhered to.
- New compliance officers will be registered with MPC as soon as they become a member of SAMED.
- MPC will send the compliance officer a voucher code which all customer facing personnel will use in order to complete the online code certification test.
- Customer facing personnel are to review the [Code](#) before taking the online code certification.
- Customer facing personnel will get three free attempts to take the online code certification whereafter there is a R500.00 fee (excl VAT) to re-take the test.
- There are 30 randomized questions to be completed.
- An annual declaration will be sent to compliance officers in February of each year which needs to be signed by the compliance officer indicating that all customer facing personnel have taken the online code certification.

### 3. User Guide documents – Online Code Certification Test

1. This guidance document provides a step by step approach for accessing the online test for certification on the Medical Device Code

[How to access the Medical Device Code of Ethical Marketing and Business Practice online certification test.](#)

2. This guidance document provides a step by step approach for locating the compliance certificate once you have successfully completed the Medical Device Code online test

[How to access the Medical Device Code of Ethical Marketing and Business Practice certificate.](#)

3. This guidance document provides Compliance Officers (or nominated equivalent individual) a step by step to access the report of your company's member compliance with the Medical Device Code of Ethical Marketing & Business Practice on the Medical Practice Consulting (MPC) Data Warehouse.

[How to access your SAMED compliance report as a compliance officer](#)

## 4. Code Resources

1. [SAMED Medical Device Registry Principles and Position Paper](#)
2. [SAMED Position on Localisation of Venue Vetting Criteria](#)
3. [SAMED Position on Company Representatives in Theatre](#)
4. [SAMED Position on Loan Sets and Company Reps in CSSD](#)
5. [The Medical Device Code of Ethical Marketing and Business Practice](#)
6. [Overview & Quick Guide Medical Device Code](#)
  - a. Overview of Medical Device Code of Ethical Marketing and Business Practice
  - b. Quick guide: Medical Device Code of Ethical Marketing and Business Practice
  - c. SAMED Communication on revised Medical Device Code values
7. [Need a Non-binding Medical Device Code Advisory Opinion?](#)
8. [SAMED Medical Device Code Hotline Complaints](#)
  - a. SAMED Code Complaints Decision Tree
  - b. Summary & outcomes of SAMED Medical Device Code hotline complaints
  - c. SAMED Whistleblowing Posters
9. [Medical Device Code Templates](#)
  - a. Consulting Framework Agreement
  - b. Indirect Educational Grant Agreement
  - c. Response to request for funding of year end events and entertainment
10. [Indirect Sponsorship and Educational Grants](#)
  - a. SAMED Guidance Document pertaining to the Management of Indirect Sponsorship and Associated Educational Grants
  - b. Training Presentation: Management of Indirect Sponsorship and Associated Educational Grants
  - c. Training Presentation: Grants and Charitable Donations
  - d. Training Presentation: Sponsorship Scenarios
  - e. Template: Indirect Educational Grant Agreement
11. [SAMED on Conference Venues](#)
12. [Internal Code Training Resources](#)
  - a. Overview of the Medical Device Code of Ethical Marketing and Business Practice
  - b. Facilitator Toolkit: Facilitator Guide
  - c. Facilitator Toolkit: Facilitator Presentation
  - d. Arrangements with consultants and Fair Market Value
  - e. Demonstration Products and Samples
  - f. Training Presentation: Grants and Charitable Donations
  - g. Training Presentation: Sponsorship Scenarios
13. [User Guides: Code Online Certification Test](#)
  - a. User Guide: How to access the Medical Device Code of Ethical Marketing and Business Practice online certification test
  - b. User Guide: How to access the Medical Device Code of Ethical Marketing and Business Practice certificate
  - c. User Guide: How to access your SAMED compliance report as a compliance officer
14. [Guidance on Emergency Support During Covid-19 crisis](#)
15. [COVID-19 compliance guidance document](#)
16. [18 A & 18 B Exemption Notice for Medtech](#)

## 5. [Anonymous Whistleblowing Hotline](#)

Whistleblowing is recognised as the most effective measure to guard against fraudulent or unethical activity within organisations. The Medical Device Code whistleblowing hotline is an anonymous tip-off mechanism available to any SAMED member and members of the public wishing to report contraventions of the Code. The hotline is independently managed and available 24/7.

Contact the Medical Device Code Hotline:

- Free call: 0800 00 04 68
- E-mail: [samed@tip-offs.com](mailto:samed@tip-offs.com) accompanied by completed complaint form
- [Download Complaint Form](#)