

Medical Device Code of Ethical Marketing and Business Practice

Transgression Report Form

Any person, including but not limited to, a SAMED member, signatory to the Code, member of the public, healthcare professional, healthcare organisation, or regulatory body may report a transgression.

Reports by a SAMED Member and/or signatory to the Code, should where possible be initiated and administrated by the Compliance Officer and / or CEO of the Company.

For hotline reports, send the form to: samed@tip-offs.com

Alternatively, a report may also be submitted directly to SAMED: secretariat@samed.org.za

Date: _____

1. Complainant (do not complete if you wish to remain anonymous):

- a. Name and surname: _____
- b. Job title: _____
- c. E-mail address: _____
- d. Mobile Number: _____ Work Number: _____
- e. Name of Company / organisation: _____
- f. Name of Company CEO: _____
- g. Field of business of the complainant (manufacturer, distributor, doctor, private hospital, member of the public etc) _____

2. Details of the individual / Company who is the subject of the alleged transgression, i.e. 'the respondent'

- a. Name and surname: _____
- b. Job title: _____
- c. Name of Company / organisation: _____
- d. Contact details of this person (if you have them):
 - E-mail address: _____
 - Mobile Number: _____ Work Number: _____

3. Field in which transgression has occurred (e.g. insulin pumps, orthopaedic implants, wound care, etc)

4. Clause(s) within the Medical Device Code, detail and circumstances relating to the alleged transgression. Succinctly describe the essence of the transgression in the table below. Use one line for each transgression. Where available list and attach any proof/evidence substantiating the reported transgression.

| Indicate Code Clause (s) | Describe each alleged transgression i.e. what, how, where | Date/period of the alleged transgression | Indicate proof/evidence substantiating the reported transgression |
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