Company letterhead (CAB)

DECLARATION OF CONFORMITY

I, [PRINT FULL NAME]

as the appointed legal representative for

*……………………………………………………………………………………………………* [FULL COMPANY NAME]

………………………………………………………………………………… [COMPANY REGISTRATION NUMBER]

………………………………………………………………………………………………….[FULL PHYSICAL ADDRESS]

hereby declare and confirm

1. that the scope of auditing activities conducted by

……………………………………….………………………………………………………….. [FULL COMPANY NAME] includes

* + the inspection and audit of manufacturers, distributors and wholesalers for compliance of the Quality Management System to ISO 13485 standard; and
  + review of compliance with the requirements of the South African Health Products Regulatory Authority (SAHPRA); and
  + review of compliance to the Medicines and Related Substances Act No. 101 as amended and Regulations; and
  + review of compliance to the Hazardous Substances Act 15 as amended and Regulations; and

1. that [COMPANY NAME] is designated /

recognised by the [PROVIDE NAME of the MEDICAL

DEVICE REGULATORY AUTHORITY], and

c. that *……………………………………………………………………..………....* [COMPANY NAME] is accredited by the signatory members to International Accreditation Forum Multilateral Arrangement (IAF MLA)) namely

…………………………………………………… to perform conformity assessment of medical device and IVD’s

establishment to ISO 13485 requirements and Local National Regulatory requirements

*Name:*

*Date of accreditation:*

*Accreditation number: (ensure to attach the accreditation certificate)*

Signed Date

Designation & qualification:

\* accreditation certificate to be attached.