

## Statement of Scope

The scope of certification (Technical areas) for IBRATSA in terms of the current version of ISO/IEC 13485 Medical Devices as read with the IAF MD 9 includes Invitro Diagnostic Medical Devices, Implantable devices and Parts and Services for Medical Devices .

The details of current scope are below:

### 1.1. Invitro Diagnostic Medical Devices

- i) In Vitro Diagnostic (IVD) Instruments and software.
- ii) Reagents and reagent products, Calibrators and control materials for Clinical Chemistry, Immunochemistry (Immunology), Haematology, Haemostasis, Immunohematology, Microbiology, Infectious Immunology, Histology (Cytology) and Genetic testing.
- iii) IVD Medical Devices other than specified above.

### 1.2. Parts and Services

- i) Maintenance (Installation)
- ii) Other Services- Decontamination of Devices

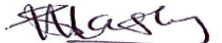

### 1.3. Non-Active Medical Devices

- i) Non-active implants

For clients whose Medical Device categories are not listed above and those who require ISO9001; certification services are offered as part of IBRATSA's Scope extension.

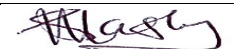



Dr. Felistas Mashinya-Managing Director

Reviewed by	Operations Director 	Review Date	27/05/2024
Approved by	Managing Director 	Approval Date	31/05/2024
Date of Implementation	10/06/2024	Revision No/Issue No.	1/1

## History of Document Changes

Rev No./ Issue No.	Date	Description of Changes	State (Approved / Not Approved)	Change Initiator (Initials)	New Rev No./ Issue No.
0/1	01/09/20	Initial Release	Approved	FM	0/1
0/1	20/09/22	Updated the Statement of Scope to include Invitro Diagnostic Medical Devices & Parts and Services-Maintenance	Approved	FM	0/2
0/2	08/06/23	Corrected the IAF MD 9 year on the document from IAF MD: 2017 to IAF MD 9: 2022.	Approved	FM	0/3
1/3	10/06/2024	New Rev/Issue as part of the Re-coding and re-structuring of QMS documents	Approved	FM	1/1

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