

CONFORMITY ASSESSMENT BODY (CAB) REQUIREMENTS FOR RECOGNITION by SAHPRA CHECKLIST

- Completed declaration indicating compliance with South African regulatory requirements

- Valid ISO 17021 Conformity assessment — Requirements for bodies providing audit and certification of management systems certificate

- Scope of work (include regulations and Act)

- Certificate indicating that they are a member of ILAC (IAF MLA)

- For a CAB which is accredited by a body other than SANAS, evidence of recognition / designation by the relevant medical device regulatory authority of that jurisdiction.