Legal
Legal framework: Yes
Authorizing legislation: Arrêté N° 2013-537/MS/CAB portant réglementation des dispositifs médicaux de diagnostic in vitro (DMDIV) et des consommables médicaux
Arrêté conjoint N°2013-1125/MS/MEF portant conditions d’octroi, de retrait et de renouvellement d’agrément technique pour la fourniture de réactifs et de consommables médicaux, la fourniture, l’installation, la mise en service et la maintenance de matériel et d’équipements medico-techniques
Guidelines: N/A

National Regulatory Authority
National Regulatory Authority present: Yes
Name: Direction générale de la pharmacie, du médicament et des laboratoires
http://www.dgpml.sante.gov.bf/
Responsibilities of the NRA: N/A

Medical device definition
Medical device defined: Yes
Notes: Definition of a medical device is harmonized with the GHTF definition.
Text: Medical device means any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article
A. Intended by the manufacturer to be used alone or in combination for human beings for the purpose of: i. diagnosis, prevention, monitoring, treatments or alleviation of disease ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury; iii. investigation, replacement or modification, or support of the anatomy or of a physiological process; iv. support or sustaining life; v. control of conception; vi. disinfection of medical device; or vii. providing information for medical or diagnostic purpose by means of in vitro examination of specimens derived form the human body, which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its intended function by such means.
In vitro diagnostic medical device (IVD) defined: Yes
Text: Defined separately.
Harmonized to EU Directive 98/79/EC.

Medical device classification
Classification: Yes
Categories: Burkina Faso has a risk-based classification system for IVDs.
Class A,B,C,D
Classification rules: N/A
Classification rules details: N/A

Essential principles
Essential principles: N/A
Details: N/A

Conformity assessment
Conformity assessment bodies: N/A
Details: N/A
Pre-marketing / procedure: There is a conformity assessment procedure for IVDs.
Arrêté N° 2013-537/MS/CAB

Reliance
Reliance: Yes
Details: Arrêté N° 2013-537/MS/CAB
Jurisdictions: EU, USA

Clinical investigation
Clinical investigation controls: Yes
Details: Arrêté N° 2013-537/MS/CAB
Registration and listing
Registration of establishment: Yes
Details: Arrêté conjoint N°2013- 1125/MS/MEF portant conditions d'octroi, de retrait et de renouvellement d’agrément technique pour la fourniture de réactifs et de consommables médicaux, la fourniture, l'installation, la mise en service et la maintenance de matériel et d'équipements medico-techniques
Listing of medical devices: Yes
Details: Listing is required for some medical devices. Criteria are based on the risk classification of medical devices.

Import controls
Import controls: Yes
Details: Each importer must submit an importation application to verify that the IVD is registered. All other medical devices are merely listed when imported.

Post market controls
Post Market Surveillance: N/A
Details: N/A
Inspection (QMS): Yes
Details: Arrêté N° 2013-537/MS/CAB, Art.21
Enforcement: N/A
Details: N/A
Adverse event reporting: Yes
Details: Burkina Faso has adopted the EU definition of an adverse event. Manufacturers, importers, wholesalers, distributors, and users are responsible to report adverse events. See survey
Field safety corrective action monitoring: Yes
Details: Manufacturers, importers, wholesalers, distributors and end-users are mandatorily responsible for carrying out Field safety corrective action (FSCA) for medical devices.
Advertising: N/A
Details: N/A
Labelling: Yes
Details: Arrêté N° 2013-537/MS/CAB.