Kigali, 13/11/2020
Ref. N°: DAR/ 2670 /FDA/2020

RWANDA FDA
Rwanda Food and Drugs Authority

P.O. Box 84 Kigali
info@rwandafda.gov.rw
www.rwandafda.gov.rw

Re: Circular on registration of Human and Veterinary Medical devices and In Vitro Diagnostics (IVDs)

Reference is made to the Law N° 003/2018 of 09/02/2018 establishing Rwanda Food and Drugs Authority (Rwanda FDA);

Further reference is made to the technical regulations N° CBD/TRG/012 Rev_0 governing registration of medical devices especially in its article 6 and 7;

Due to substantial contribution of Medical devices and In Vitro Diagnostics (IVDs) in the diagnosis, testing, vaccination, cure, surgery, and in Human & Animal health protection; In order to protect the public health, the Authority wishes to inform all local and foreign stakeholders including manufacturers, importers/distributors, and local technical representatives that Human and Veterinary medical devices and In Vitro Diagnostics (IVDs) are required to be registered by the Authority.

Subsequently, the Authority wishes to inform the manufacturers and importers of Human and Veterinary medical devices and In Vitro Diagnostics (IVDs) the following:

1. All applications for registration of Human and Veterinary medical devices on market shall be prepared and submitted to Rwanda FDA according Rwanda FDA guidelines on submission of documentation for registration medical devices and a proof of payment of non-refundable registration fee prescribed in the Technical regulation N° CBD/TRG/004 Rev_1 related to regulatory service tariff and fees shall be submitted.

2. All applications for medical devices and In Vitro Diagnostics (IVDs) shall be submitted along with samples where applicable. Please note that applications for medical devices and In Vitro Diagnostics (IVDs) registration can only be made using a Compact Disc (CD) or external Driver, which should be handed to the Rwanda FDA reception along with the cover letter and application form.
3. All stakeholders including distributors and manufacturers shall be required to comply with the above communique and the application for medical devices and in vitro diagnostics registration should be submitted not later than **30th June 2021**.

Thereafter a list of registered medical devices and IVDs will be published on Rwanda FDA website. All Human and Veterinary medical devices and IVDs which will not be

on that list, will be considered as not registered and shall not be permitted to be imported, sold or distributed on Rwandan market.

We thank you for your consideration

Sincerely,

Digitally signed by Rwanda FDA (Ag DG)
Date: 2020.11.16 22:30:03 +02'00'

Dr. Charles KARANGWA
Ag. Director General

RWANDA FDA
Rwanda Food and Drugs Authority