RWANDA FDA
Rwanda Food and Drugs Authority
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Kigali, 09/07/2021
Ref. N°: DAR/CRC/ 2398 /FDA/2021

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) to regulate food and drugs;

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

Reference is also made to the previous issued circular N° DAR/2670/FDA/2020 issued on 13/11/2020. Considering the current situation of Covid-19 pandemic, the Authority would like to inform all stakeholders including manufacturers, importers/distributors, and local technical representatives that Human and Veterinary medical devices that the period for application submission is extended for six (6) months. Please note that the deadline for application for registration of IVDs will be communicated when the guidelines on submission of documentation for registration of IVDs will be approved and published.

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 paid.

2. All applications for medical devices shall be submitted along with samples where applicable. Please note that applications for medical devices 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 communiqué and the application for medical devices registration should be submitted not late than **31st January, 2022**

Thereafter a list of registered medical devices will be published on Rwanda FDA website. All Human and Veterinary medical devices which will not be on that list, they will be considered as not registered and shall not be permitted to be imported, sold or distributed on Rwandan market.

This circular is effective from 10th July 2021.

Sincerely,

Digitally signed by
Rwanda FDA (Ag DG)
Date: 2021.07.09
17:08:34 +02'00'

Dr. Charles KARANGWA
Ag. Director General