QMS No: DFAR/HMDAR/FMT/001

Revision No: 1

Effective Date: 16/06/2022

**Cover Letter**

<Applicant>

<Address>

<Postal Code><Town>

<Date>

<Applicant’s reference>

<Rwanda FDA>

<P.O.Box:1948><Kigali\_Rwanda>

Dear Sir/Madam,

**Subject: Submission of Application Dossier(s) for Marketing Authorization of < Medical device(s) >**

We are pleased to submit our Application Dossier(s) for the registration of medical devices/In Vitro Diagnostics Devices (IVDDs) that details are as follows:

**Name of the Medical device(s) /IVDD(s):** ………………………………….……………………..

**Classification of the Medical Device(s)/IVDD(s):** …………………………………………….…..

**Intended use of the Medical Device(s)/IVDD(s):** ……………………................................

You will find enclosed the submission dossier as specified hereafter:

* Two (2) CD rom/external driver that contains the summary of technical documentation (STED) in selectable PDF format
* The proof of payment.
* We confirm that the electronic submission has been checked with up-to-date and state-of-the-art antivirus software.
* Type of Submission: 󠇯󠇯Full registration Application 󠇯󠇯Abridged Application 󠇯notification 󠇯
* sample(s) submitted
* Application for QMS audit/GMP inspection has been made to Rwanda FDA (as per relevant guidelines)
* I confirm that the Product Dossier information submitted is the same in all aspects as the product registered with the relevant SRA, WHO PQ and EAC (Only for Abridged Applications)

I, the undersigned certify that all the information in this form and accompanying documentation is correct, complete and true to the best of my knowledge

Yours sincerely,

<Signature>

<Name>

<Title>

<Phone number(s)>

<Email address>