Regulatory approval process of COVID-19 personal protective equipment (PPE)

1. General

All personal protective equipment (PPE) that is intended for use as a medical device must follow the EFDA regulations and should meet applicable requirements. The EFDA regulates personal protective device that are used in healthcare settings such as hospitals, doctor's offices, quarantine areas and clinical labs. When used properly, PPE acts as a barrier between infectious materials such as viral and bacterial contaminants and your skin, mouth, nose, or eyes (mucous membranes). Those PPE includes Medical mask, coverall gowns, face shield, shoe cover, goggles etc.
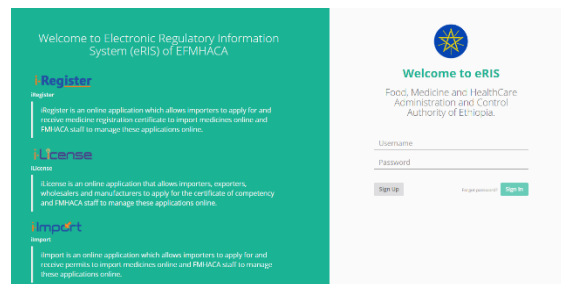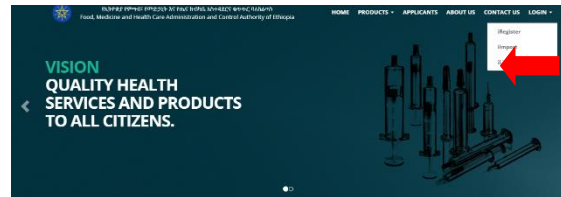
2. Steps of getting regulatory approval

2.1. Step 1: i-license online applications
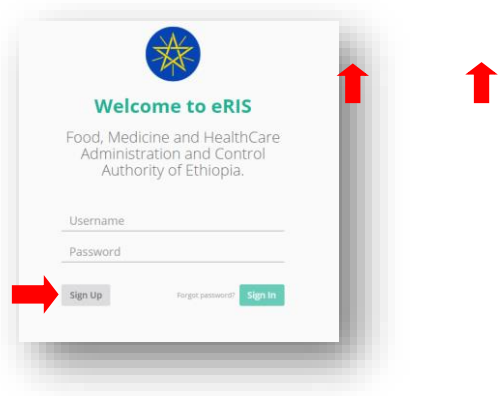
How to Create eRIS account for i-License

Sign Up Process

1. To sign up and start the application process, first go to the web address below:
https://ilicense.efda.gov.et/

2. You will be directed to this page where you can Signup or Sign In if you already have an Account

3. Click **on Sign Up Button**

4. Enter the **Applicant information**:

NOTE:
- **The user name and password you enter here is used to login your account. You have to remember it.**
- **The email and password you enter here will be used to send you notifications. Please use a valid email and phone number**
- **If you don't have an email please create an email https://www.google.com/gmail/**

How to create Temporary COC application on i-License

 Temporary COC Application Request Process

1. Log in to i-License using your user name and password https://ilicense.efda.gov.et/

2. Click **New Temporary application**

3. Enter **Facility information** and click next when you finish. Then proceed filling the **Facility Address**

4. Continue entering **Facility Professionals**

5. Upload attachments by clicking on **File Attachment**and upload your documents. Make sure your files are in **.pdf** format

6. Click the **Submit** button when you finish. Your application is accepted when you see the notice "**Application submitted successfully**" appears

2.2. **Step 2: Screening of the i-license application.**

The application will be evaluated by the EFDA customer service officer (screener) and if comply with the application requirement, assigned for inspection. If not comply with the application requirement, the applicant will edit the application according to the comment given by the EFDA customer service officer.

2.3. **Step3**: **Conducting inspection.**

The inspection will be conducted jointly by the head office inspectors and branch inspectors according to the EFDA temporary licensing requirement.

2.4. **Step4**: **Preparation of inspection report and evaluation of the inspection report.**

The inspection report will be prepared by the inspectors and evaluated by the technical team with the presence of the MFID director and provide the inspection report to the manufacturer (whether it is Comply/not comply to manufacture the PPE)

2.5. **Step5:** If the report complies to manufacture PPE**,** the branch office will issue the **certificate of competency to manufacture COVID-19 PPE**. After the manufacturer collected the COC, they can manufacture the PPE and the product tested for performance quality parameters. Like: - Bacterial efficiency test and breathability test for medical face mask. Pathogen penetration resistance test and fluid penetration resistance test for cover all gowns and etc…

2.6. **Step 6: Registration of the product.**

The manufacturer shall submit the test result along with other product registration requirement through i-register (abbreviated requirement) for registration of products. If the applicant comply the requirement, the **EFDA head office will grant temporary market authorization for six month**.