የኢትዮጵያ መድኃኒት አቅራቢ ኤጀንሲ
Ethiopian Pharmaceuticals Supply Agency

ቀን Date 05 JAN 2023

ቁጥር Ref. No. EPSA/06/587/01

To: All participants of tender with Ref. No. ICB/EPSA6/MoH-SDG/Neuro/MD/20/22

Subject: Clarification on tender with ref. No. ICB/EPSA6/MoH-SDG/Neuro/MD20//22

Dear Sirs,

Reference is made to the above captioned tender. We hereby clarify that the evaluation will be done as per the priority given below:-

1. **First Priority:** Valid Product Certificate from EFDA & Valid Product Certificate from **SRA** Region;
   In case of no bidder with 100% line item under 1st priority:

   - Bidders with more line item under 1st priority (EFDA & SRA) registered from the lot item will be given priority than bidders with less item registered (SRA & EFDA). Bidders without Valid Product Certificate from SRA Region will be rejected

2. **Second Priority:** Valid Product Certificate from **SRA** Region;

The Valid Product Certificate from **SRA** Regions are:

S.No.	Stringent Regulatory Authority (SRA)	Remark
1	US Food and Drug Administration, USA	
2	Ministry of Health, Labor and Welfare, Japan	
3	Therapeutic Goods Administration (TGA), Australia	
4	Health Science Authority, Singapore	
5	Competent Authorities from one of the 27 Member States of the European Union who are responsible in Europe for the oversight of Directive 93/42/EEC, Directive 98/79/EC, MDR 745/2017, IVDR 746/2017, 90/385/EEC Active Implantable medical devices.	Please Refer link: https://ec.europa.eu/growth/tools-databases/nando/index.cfm?fuseaction=directive.main
6	Medicine and Healthcare Products Regulatory Agency, UK	
7	Health Canada, Canada	
8	Ministry of Food and Drug Safety, South Korea	

We hope the above points clarify your request.

With Best Regards

Tsegabu Hailu Mogessie
Pharmaceuticals & Medical Supplies Procurement Management Directorate
P/Director

Ethiopian Pharmaceuticals Supply Agency

CC:

- Deputy Director General (Inbound Logistics)
- Medical Device Tender Management Team
- Archive
  EPSA

Tel. 011-275 17 70 | 011-275 06 74 | 011-276 06 76 | 011-276 32 65 (Director General Office) | 011-276 32 73 | 011-276 32 66
011-275 93 24 (HR) | 011-276 32 72 (Distribution Directorate) | 011-276 32 68 (Fund Directorate) | Fax. 011-275 25 55 | 011-155 32 77
e-mail: info@epsa.gov.et | P.O.Box- 21904, Addis Ababa, Ethiopia | www.epsa.gov.et