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Date

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Ref. No. EPISA/06/586/04

To: All participants of tender with Ref. No. ICB/EPISA6/RDF-Routine/MD/10/22

Subject: Clarification on tender with ref. No. ICB/EPISA6/RDF-Routine/MD/10/22

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 Specific Certificate from EFDA (for Quoted Model) & Valid Product specific Certificate from SRA Region (WHO Certificate for Refrigerators);
2. **Second Priority:** Valid Product specific Certificate from SRA Region (WHO Certificate for Refrigerators);
3. **For Laundry Machine:** - Valid Product Specific Certificate of Directive 426/2016/or Full Product Quality Assurance from SRA Region.

The Valid Product Specific Certificate from SRA Region 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, Directive 426/2016.	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

CC:

- Deputy Director General (Inbound Logistics)
- Medical Equipment Tender Management Team
- Archive
EPISA

