

ANNEX B

DOCUMENT CHECKLIST TO BE SUBMITTED WITH CONSIGNMENT PROPOSAL

Minimum Verifiable Documents		Yes	No
Legal (Qualification Documents)			
1)	PhilGEPS registration certificate.		
2)	Any of the following documents defining the business status and arrangement of the Prospective Consignor (a) If the Prospective Consignor is a manufacturer, certify that the Prospective Consignor manufactures the products/items; or (b) If the Prospective Consignor is an Exclusive/Authorized Distributor or Dealer of the products/items, Certificate or Contract from the manufacturer must be provided as proof that the bidder is an Exclusive/Authorized Distributor or Dealer of the products/items; or (c) If the Prospective Consignor is an agent of the exclusive distributor or dealer, a Certificate or Distributor/Dealership Agreement by the Manufacturer with the distributor or dealer; and/or Contract between the distributor/dealer and the Prospective Consignor		
Financial Documents & Track Record			
3)	Audited financial statement showing, among others, the Total and Current Assets and Liabilities, stamped "received" by the Bureau of Internal Revenue (BIR) or its duly accredited and authorized institutions, for the preceding calendar year, which should <i>not be earlier than two (2) years from the date of the submission of the proposal</i>		
4)	At least three (3) sample contracts for procurement of medical devices and supplies or machine-tie-up preferably consignment Agreements in the past 3 years in a public or private health facility with copies of delivery acceptance		
5)	Computation from utmost 3 contracts/Agreements from previous Consignees, or Procuring Entities of accepted supply of medical device and supply depicting comparison of total cost of completed contracts/Agreements to the total cost what is/are being proposed to be consigned to the Health Facility by Prospective Consignor.		
Technical Documents			
6)	Valid and current License to Operate (LTO) as Medical Device Importer/ Wholesaler issued by Philippine Food and Drug Administration (FDA). In case of expired LTO , the following copies may be submitted provided that in case of expired LTO, the application for renewal was timely made as per FDA Circular No. 2011-004:		
Minimum Verifiable Documents		Yes	No
	a) Expired LTO; b) Application for renewal; and c) Official Receipt as proof of payment of renewal of LTO		
FOR EACH ITEM AS APPLICABLE			
7)	If applicable, Certificate of Product Registration based on FDA Memorandum Circular No. 2004-005 or latest issuance or any of the following certificates based on AO No. 2018-0002 whichever is applicable once fully implemented by the FDA: (a) Certificate of Medical Device Notification (b) Certificate of Medical Device Registration/ Certificate of Product		

	Registration (c) Certificate of Medical Device Listing		
8)	If applicable and necessary to ensure quality: (a) WHO Prequalification Certificate/ Dossier/ Listing (b) ISO 13485:2016 and/or ISO 9001 :2015 and/or relevant IEC 60601 standard Certificates or other related quality management standards		
9)	Original brochure or downloaded from internet or product insert/information or other technical documentations. In case of photocopies, it must be duly certified as true copy or faithful reproduction of the original by the Prospective Consignor		
OTHER DOCUMENTS TO BE SUBMITTED BY THE PROSPECTIVE CONSIGNOR			
	Company Profile		
	Guarantee letter from the Prospective Consignor, indicating the following: [Select when appropriate] (a) Provide the correct, quality and necessary specifications of the device/supply including sterility when needed; (b) Provide the special instrumentation for the use of the device, such as, for implants, when appropriate (c) To honor the delivery schedules and to replace expiring items when returned [X] months before expiry date. (d) Compliance to Department Order No 2019-[xxxx) on the Guidelines of Consignment of Medical Devices and Supplies		
10)	Duly notarized authority of the signatory (a) Secretary's Certificate (i.e., Corporation; Joint Venture Agreement); or (b) Special Power of Attorney (i.e., Sole Proprietorship; Partnership)		
CONSIGNMENT PROPOSAL			
11)	Duly accomplished and signed Consignment Proposal		