

Level 1 Category: Medical Equipment and Accessories and Supplies -UNSPS Code 42000000

Level 2 Category: Dialysis equipment and supplies - UNSPS Code 42160000

Level 3 Category: Extracorporeal hemodialysis equipment and supplies -UNSPS Code 42161600

Level 4 Category: Dialyzer Reprocessing system -UNSPS Code 42161615

DRAFT
T/P

GEM Version 3.0

S.NO	PARAMETER	HINT	TYPE OF FIELD	VALUES	UNIT	CATEGORY OF FIELD	REMARKS
GENERAL FEATURES							
1	Product name	--	ENUMERABLE	Automatic Dialyzer Reprocessing System/machine		MANDATORY	
2	Clinical purpose	--	ENUMERABLE	Dialysis of blood and also to reprocess the used dialyzer for its re-use on the same patient		MANDATORY	
3	Patient category	--	ENUMERABLE	Pediatrics and adults		MANDATORY	
FUNCTIONAL FEATURES							
1	Material of the body	--	ENUMERABLE	Polypropylene (PP)		MANDATORY	
2	Fully automatic reprocessing and disinfecting cycles	--	ENUMERABLE	Yes		MANDATORY	
3	Clean and sterilize different high and low flux dialyzers	--	ENUMERABLE	Yes		MANDATORY	
4	Clean sterilize and inspect one or more dialyzer at the same time of different models	--	ENUMERABLE	Yes		MANDATORY	
5	Venous Line Clamp for secure venous outlet line	--	ENUMERABLE	Yes		MANDATORY	
6	Built-in anti-splash proof design	--	ENUMERABLE	Yes		MANDATORY	
7	Built-in effluent basin	--	ENUMERABLE	Yes		MANDATORY	
8	Innovative constant pressure flush device	--	ENUMERABLE	Yes		MANDATORY	
9	Performs Membrane broken experiment and pressure leak test	--	ENUMERABLE	Yes		MANDATORY	
10	Detects membrane integrity & imperfections	--	ENUMERABLE	Yes		MANDATORY	
11	Low water process alarm	--	ENUMERABLE	Yes		MANDATORY	
12	Chemical detection sensor	--	ENUMERABLE	Yes		MANDATORY	
13	Chemical concentration sensor	--	ENUMERABLE	Yes		MANDATORY	
14	Dialyser disinfectant fill sensor	--	ENUMERABLE	Yes		MANDATORY	
15	Automatic steriliant filling	--	ENUMERABLE	Yes		MANDATORY	
16	Compatible with all cold steriliants	--	ENUMERABLE	Yes		MANDATORY	
17	Processes all kinds of hollow fiber dialyzers	--	ENUMERABLE	Yes		MANDATORY	
18	Detects the Volume loss & leakage of dialyzer	--	ENUMERABLE	Yes		MANDATORY	
19	Compatible to use various chemicals to disinfect dialyzers	--	ENUMERABLE	Yes		MANDATORY	
20	Automatic disinfectant dilution indication	--	ENUMERABLE	Yes		MANDATORY	
21	Capable to Perform separate cycle test for ease of taking of water samples	--	ENUMERABLE	Yes		MANDATORY	
22	Capable to perform diagnostic test to verify that the header is on securely with "O" ring in place	--	ENUMERABLE	Yes		MANDATORY	
23	Dedicated clean/rinse cycle for heavily deposited lines	--	ENUMERABLE	Yes		MANDATORY	
24	Automatic processing cycle time (cycle for rinse, clean, test and disinfectant to affuse dialyzers automatically), minutes/cycle	Must declare, 8<N<15	NUMERIC	Range: 8 to 15	minutes/cycle	GOLDEN PARAMETER	

25	Cleaned dialyzer identification with a sticker pasted on it for reuse	--	BOOLEAN	Yes					--	MANDATORY	
26	Color coding to provides visual cues to dialyzer orientation	--	ENUMERABLE	Yes					--	MANDATORY	
27	Dialyzer discard allowed after 60% of actual priming value repeated use	--	ENUMERABLE	Yes					--	MANDATORY	
28	Size (LxWxH) (mmxmmxmm)	--	ENUMERABLE	470x380x480	480x380x580	430x355x500		mmxmmxmm		GOLDEN PARAMETER	
29	Weight (Kg)	--	NUMERIC	25	30	35	38	Kg		GOLDEN PARAMETER	
ELECTRICAL FEATURES											
1	Power supply	--	ENUMERABLE	220+/-10% V, 50/60 Hz, AC Single phase					--	MANDATORY	
2	Input power (Watts)	--	NUMERIC	125	130	145	150	watt		GOLDEN PARAMETER	
3	Compliance to IS:302-1/2008 in respect of electrical safety requirements	--	ENUMERABLE	Yes					--	MANDATORY	
USER INTERFACE											
1	LCD touch screen colour display	--	ENUMERABLE	Yes					--	MANDATORY	
2	Printer to print Name, Tag & Test Result	--	ENUMERABLE	Built-in	External				--	GOLDEN PARAMETER	
3	Data protection while power goes off	--	ENUMERABLE	Yes					--	MANDATORY	
4	Bar code scanner	--	BOOLEAN	Yes	No				--	MANDATORY,FILTER	
5	Memory for storage of records	--	ENUMERABLE	Yes					--	MANDATORY	
6	Selectable programs for all types of dialyzer	--	ENUMERABLE	Yes					--	MANDATORY	
PACKING MODE											
1	The product is packed individually in a box with all its accessories in such a way that there will be no transit damage takes place	--	ENUMERABLE	Yes					--	MANDATORY	
ENVIRONMENTAL CONSIDERATIONS											
1	Storage conditions	--	ENUMERABLE	Temperature 5 deg C to 40 deg C, RH not more than 80%					--	MANDATORY	
2	Work or usage environment	--	ENUMERABLE	Temperature 5 deg C to 40 deg C, RH not more than 80%					--	MANDATORY	
CERTIFICATIONS & REPORTS											
1	Submission of Test Report from Central Govt./NABL/ILAC accredited Lab to prove the conformity to declared specification at the time of supply	--	ENUMERABLE	YES					--	MANDATORY	
2	Product certification	--	ENUMERABLE	BIS	EU-CE	US-FDA			--	MANDATORY,FILTER	Multiselect
3	Certification, performance and safety standards specific to the device		TEXT	Must Declare like IEC 60601-1:2012, IEC 6060-1-2:2014, ISO 14971:2007					--	MANDATORY	
4	Submission of all the certifications and test reports to the buyer along with supplies on demand	--	ENUMERABLE	Yes					--	MANDATORY	
INSTALLATION & TRAINING											
1	Supplier to perform installation, safety and operation checks before handover	--	ENUMERABLE	Yes					--	MANDATORY	
2	Agreed for installation in case if machine requirement is for remote/field locations and to provide services onsite to end user	--	BOOLEAN	Yes	No				--	MANDATORY,FILTER	
2	Training of users in operation and basic maintenance shall be provided	--	ENUMERABLE	Yes					--	MANDATORY	
WARRANTY & MAINTENANCE											
1	Warranty (Yrs)	--	NUMERIC	3	4	5		Years		GOLDEN PARAMETER	
2	Provision of international warranty for 5 years	--	BOOLEAN	Yes	No				--	MANDATORY,FILTER	
2	User technical and maintenance manual detailing complete maintaining schedule with routine maintenance should be provided	--	ENUMERABLE	Yes					--	MANDATORY	
3	Contact details of manufacturer, supplier and local service agent to be provided	--	ENUMERABLE	Yes					--	MANDATORY	