

28-07-2022

Amendment no. 7

Sub: Amendment to the technical specification for the tender of PMR Department

Ref.: Bid No: GEM/2022/B/2125200, GEM/2022/B/2125137, GEM/2022/B/2125077,
 GEM/2022/B/2125040, GEM/2022/B/2124978, GEM/2022/B/2124943,
 GEM/2022/B/2124900, GEM/2022/B/2124863, GEM/2022/B/2124818,
 GEM/2022/B/2124779, GEM/2022/B/2124746, GEM/2022/B/2124708,
 GEM/2022/B/2124681, GEM/2022/B/2124598, GEM/2022/B/2124579,
 GEM/2022/B/2124568, GEM/2022/B/2124549, GEM/2022/B/2124500,
 GEM/2022/B/2124464, GEM/2022/B/2124446, GEM/2022/B/2124432 Dated
 25.04.2022

The following changes are being incorporated in the above referred GeM Bid No.

TECHNICAL AMENDMENTS

Intermittent Pneumatic Compression for Prevention of DVT (GeM tender ID: GEM/2022/B/2125137 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
1	System should consist of a 3- 4 chamber sequential compression device with a total fast filling cycle and emptying cycle total of 60 seconds approximately.	System should consist of a 3 or more chamber sequential compression device with a total fast filling cycle and emptying cycle total of 60 seconds approximately.
2	Should have disposable/reusable sleeves which offer a compression of the foot and the calf.	Should have disposable/reusable cuffs which offer a compression of the thigh and the calf.
7	The compression garment can be cleaned and reused with a warranty or 20 Nos. disposable sleeve to be provided	Reusable compression cuff 1 No each for thigh and calf should be provided and should be covered under warranty period. OR 20 Nos. of disposable cuffs should be provided for thigh and Calf.

11	Should be CE/FDA/BIS approved.	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body
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Operation Theater Surgical Instruments (GeM tender ID: GEM/2022/B/2125077 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
4	Bipolar cautery-1	Deleted
5	Monopolar cautery-1	Deleted
6	Suction Apparatus-1	Deleted
	NA	Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body

Treatment Tables with postural drainage (Bid No: GEM/2022/B/2125200 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
9	It should be European CE or USFDA certified.	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Exercise table (Bid No: GEM/2022/B/2125040 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	NA	<p>Added Para :</p> <p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Tilt table (Manual) (Bid No: GEM/2022/B/2124978 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
8)	Should be CE / FDA / BIS certified	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Tilt Table (Motorized) (Bid No: GEM/2022/B/2124943 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
14)	Should be USFDA or European CE certified.	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Parallel bar with platform (Bid No: GEM/2022/B/2124900 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS

h	Should be CE/FDA/BIS/Equivalent Certified	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>
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Recumbent Cycle Exerciser (Bid No: GEM/2022/B/2124863 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	Should Be US FDA/ European CE certified.	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Stair training unit with ramp (wooden stairs) (Bid No: GEM/2022/B/2124818 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	NA	<p>Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Wheelchair(Manual) (Bid No: GEM/2022/B/2124779 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	Desirable reclining mode Should be CE approved	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body

Motorized wheelchair (Bid No: GEM/2022/B/2124746 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	Should be CE/FDA/BIS/ Equivalent certified .	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body

Hip, knee, ankle CPM (Bid No: GEM/2022/B/2124708 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS

NA	<ul style="list-style-type: none"> System should be US FDA / european CE certified. 	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>
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Shoulder CPM (Bid No: GEM/2022/B/2124681 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	The unit should be European CE or US FDA certified.	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Ultrasonic Therapy Machine(UST) (Bid No: GEM/2022/B/2124598 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	The unit should be US FDA or European CE approved	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Cryotherapy (Bid No: GEM/2022/B/2124579 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	It should be USFDA/ European CE certified.	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body

Short wave diathermy (Bid No: GEM/2022/B/2124568 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	The unit should be European CE or US FDA certified.	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body

Moist heat therapy unit (Bid No: GEM/2022/B/2124549 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS

NA	Unit should be European CE or US FDA certified	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>
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Paraffin wax bath (Bid No: GEM/2022/B/2124500 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	NA	<p>Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Transcutaneous Electric Nerve Stimulation (TENS) (Bid No: GEM/2022/B/2124464 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	Unit should be CE certified.	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>

Lumbar and Cervical Traction (Bid No: GEM/2022/B/2124446 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	The unit should be European CE or US FDA certified	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Combination therapy unit (Portable) (Bid No: GEM/2022/B/2124432 dated 25.04.2022)		
Tender Page & Para	TENDER SPECIFICATION	AMENDED AS
NA	Should be USFDA/European CE certified	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>

Note: Following Technical Compliance Sheet Should be uploaded along with technical bid for respective items.

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2125200 dated 25.04.2022			
Name of the item :		Treatment Table with Postural Drainage			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	High quality, functional and extremely durable physiotherapy tables Angle of the Head Section should be adjustable from to -20 to 80 Degree.				
2	Width of working area of table should be 70 Cm.				
3	It should have Breathing Hole & Plug .				
4	It should have Adjustable foot for uneven flooring.				
5	It should have hand remote control.				
6	It should have electrically adjustable Height Range from to 45 to 90 cm.				
7	Table should be three sections with electrically operated postural drainage facility.				
8	Angle of leg section should be adjustable from 0 to 80 degree.				
9	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical				

Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
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<u>COMPLIANCE STATEMENT</u>					
Bid No :		GEM/2022/B/2125137 dated 25.04.2022			
Name of the item :		Intermittent Pneumatic Compression for Prevention of DVT			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	System should consist of a 3 or more chamber sequential compression device with a total fast filling cycle and emptying cycle total of 60 seconds approximately.				
2	Should have disposable/reusable cuffs which offer a compression of the thigh and the calf.				
3	The pressure range of the machine should be 50 mm Hg +/- 10%.				
4	The cycling time should be one minute - the machine repeats the compression every minute and can be run for 24 hours continuously to provide optimum DVT prevention for the patient. (Optional)				
5	It should be lightweight and noise free and vibration free.				
6	The compression sleeves should be comfortable to wear and easy to use for patients and the machine should have inbuilt alarms for monitoring.				

7	Reusable compression cuff 1 No each for thigh and calf should be provided and should be covered under warranty period. OR 20 Nos. of disposable cuffs should be provided for thigh and Calf.				
8	Provisions should be available for closing of one leg pressure vent when used on single limb.				
9	Accessories: Availability of sleeves/cuffs in three different sizes small, medium and large.				
10	It should operate on 220-230 volts/115v, 50-60 Hz				
11	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
12	Garment/Sleeves rates should be quoted separately				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2125077 dated 25.04.2022			
Name of the item :		PMR Equipment list of surgical instruments			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
General Surgical Instruments					
	(For Deformity Correction, pressure ulcer surgeries & Rehabilitation Surgeries)				
1	Sponge Holder-4				

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2	Towel Clamp (Small)-1 dozen				
3	Towel Clamp (Large - artery forceps type)-1 dozen				
4	Deleted				
5	Deleted				
6	Deleted				
7	BP Handle - for blade number 24 (Big)-3				
8	BP Handle for blade number 15 (small)-3				
9	Straight Artery Forceps (6 inch)-1 dozen				
10	Straight Artery Forceps(8 inch)-6				
11	Straight Artery Forceps (10inch)-6				
12	Mosquito straight Artery Forceps-1 dozen				
13	Curved Artery Forceps (6 inch)-1 dozen				
14	Curved Artery Forceps (8 inch)-6				
15	Curved Artery Forceps (10inch)-6				
16	Mosquito Curved Artery Forceps-1 dozen				
17	Allis Tissue Forceps (6 inch)-1 dozen				
18	Allis Tissue Forceps (8 inch)-1 dozen				
19	Allis Tissue Forceps (10 inch)-1 dozen				
20	Cockers Forceps (6 Inch)-6				
21	Cockers Forceps(8 inch)-6				
22	Thumb Forceps toothed (8 inch)-4				
23	Thumb Forceps Toothe (6 inch)-4				
24	Thumb Forceps Plane (6 inch)-4				
25	Thumb Forceps Plane (4 inch) Twizzer-4				
26	Needle Holder (8 Inch)-4				
27	Needle Holder (6 Inch)-6				
28	Needle Holder (10 Inch)-6				
29	Scissors (10 Inch)-4				
30	Scissors (8 inch) (Stitch Cutting)-4				
31	Dissecting Scissor Straight (8 inch)-4				
32	Dissecting Scissor curved (8 inch)-4				
33	Dissecting Scissor Straight (6 inch)-4				
34	Dissecting Scissor curved (6 inch)-4				
35	Pointed small scissor straight-4				
36	Pointed small scissor curved-4				
37	Lahey's Forcep (Medium) 8 inch-2				
38	Lahey's Forceps (Medium) 6 inch-2				
39	Right Angle Retractor (3 Inch)-2				
40	Right Angle Retractor (2 Inch)-2				
41	Right Angle Retractor 1.5 inch-2				
42	Right Angle Retractor 1 inch-2				
90	Bone Chisel (5mm)-1				
91	Wriggle and Saw Handle-2 pair				
92	Wriggle and Saw Wire-1 Dozen				

93	Bone file-2				
94	K wire extractor-1				
95	Small T handle for scanz pin holder-1				
96	Stainless steel wire cutter cum bender and plier (Large)-1				
97	Stainless steel wire cutter cum bender and plier (Small)-1				
98	Plate Bender-1 Set				
Plaster Cutting Set					
99	Electric Plastic cutter-1				
100	Manual Plaster Cutter-2				
101	Plaster Spreader-2				
102	Plaster cutting scissor-2				
Ilizarov Set of Instrument					
103	Heavy Duty Pliar-1				
104	Ilizarov wire cutter-1				
105	Rench for sixe no 9 and 10-nut/bolt-6				
106	Box Rench for size 10-nut/bolt-2				
107	Wire rensioner-2				
108	Dynamometer for giving wire tension-2				
109	Screw driver 4.5mm-2				
110	Screw Driver 3.5 mm-2				
111	Bone tap 4.5 mm-2				
112	Bone tap 3.5 mm-2				
113	Drill Sleeve - 4.5 mm and 3.5mm-2				
Tendon Transfer Instruments					
114	Tendon Tunneller-Large-1				
115	Tendon Tunneller- Medium-1				
116	Tendon Tunneller- Small-1				
117	Tendon Passer Straight Large-1				
118	Tendon Passer Straight Medium-1				
119	Tendon Passer Straight - Small-1				
120	Skin Grafting knife (Humpy)- 6 Inch Blade Holder-1				
121	Skin Grafting knife - 2 Inch Blade Holder-1				
122	Bone Curetter Large-1				
123	Bone Curetter Small-1				
124	Skin Hooks - Single and double prong-2				
125	Self retaining retractor (Medium)-1				
126	Self Retaining retractor (Small)-1				
127	Bone Awl straight-1				
128	Bone Awl curve-1				
	Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System				

	OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
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<u>COMPLIANCE STATEMENT</u>		-			
Bid No :		GEM/2022/B/2125040 dated 25.04.2022			
Name of the item :		Exercise Table			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES - Give Comments	Remarks
1	Smooth Wooden Exercise Table				
2	Plain table (Wooden table) with adjustable-hack 2" upholstered top.				
3	Adjustable hack features positive locking in 6-8 places				
4	Top : 150 cm x 88 cm				
5	Provided with 6 legs				
6	Special frame design allows 1000 pound patient capacity				

7	<p>Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>			
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COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124978 dated 25.04.2022			
Name of the item :		Tilt Table (Manual)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Manually operated tilt table with foam padded top				
2	Provided with three straps to hold the patient- Thoracic, Pelvic and Knee				
3	Range of tilt calibrated from 0-90 degree				
4	Table top is 61 cm wide x 198 cm long x 80 cm high				
5	Fitted on heavy duty tubular steel frame with locking castors for easy mobility				
6	Oven baked finish				
7	Provided with two griping handles				

	for various activities.				
8	<p>Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body</p>				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124943 dated 25.04.2022			
Name of the item :		Tilt Table (Motorised)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Table should have electric height adjustment control via remote from 46 to 84 cm				
2	It should have electric tilting control via remote.				
3	Both control can be adjust by two function hand remote.				
4	Table should tilt full 90 degree				
5	tilt tables motor should have 12-14 mm/sec speed at unloaded and 6 -7 mm/sec speed at full load.				
6	It should have Battery Back-Up to bring the patient down in case of				

	power failure				
7	It should have facility of lowers to wheelchair height				
8	It should have good quality large braking castors				
9	It should indicate tilt angle.				
10	Table should have minimum 200 kg weight barring capacity of patient.				
11	Table top should have minimum 61cm wide x 198cm long x 80cm high				
12	Table should have minimum Three fixation belts:- Thoracic, Pelvic, Knee				
13	Table should have work table attachment.				
14	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124900 dated 25.04.2022			
Name of the item :		Parallel Bar with Platform			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
a	The Length of Parallel Bar will be 12 feet, Width adjusts from 15" to 28" with ergonomic control knobs on each upright.				
b	Mounted on a wooden Platform, provided with Mirror.				

c	"anti-slip" treads on each end				
d	1.5 diameter one piece stainless steel handrails.				
e	Heavy gauge black powder coated steel uprights and fittings.				
f	Each upright telescopes up in 1.5 increments and locks into various height positions with fail-safe ball-tip locking pin.				
g	Weight Capacity: more than 200 lbs.				
h	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

<u>COMPLIANCE STATEMENT</u>					
Bid No :		GEM/2022/B/2124863 dated 25.04.2022			
Name of the item :		Recumbent Cycle Exerciser			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Cycle should have following program				
2	Hill,Interval, Manual/Track, Random , Weight Loss HRC, Quick Start and should be with 2 to 4 user IDs.				
3	Cycle should have Infrared remote control, Lumbar pouch,				
4	Cycle should have Adjustable seat pad, Adjustable seat back				
5	Cycle should have Feed back display for Speed, watts, calories, RPM , Distance, Time,Resistance level, HR and Targeted HR.				

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6	Cycle should have LED display and should be adjustable with out pedaling				
7	Cycle should be capable for Max user weightup to 400 lbs				
8	Cycle should have Mini 15- 20 electro magnetic resistance level .				
9	Cycle should have Self-generating power supply with 2 minute backup				
10	Cycle should supply with hot and cold pack to be place in lumber pouch				
11	<p>Manufacturer should have ISO 13485:2016 certification issued from :</p> <p>Any Certification Bodies registered with NABCB under Medical Devices Quality Management System</p> <p>OR</p> <p>Any notified body registered with CDSCO</p> <p>OR</p> <p>Any 4-digit CE notified body</p>				

<u>COMPLIANCE STATEMENT</u>					
Bid No :		GEM/2022/B/2124818 dated 25.04.2022			
Name of the item :		Stairs Training Unit (Wooden stairs)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Wide platform for patient: Enough to change direction with crutches				
2	Built in two sections fit in STRAIGHT				
3	Step Arrangement : four 15 cms steps leading to platform of 76 x 76 x 60 cms high				
4	Hand rails at different height to accommodate adult and children.				
5	Sides and supporting frame of steps is made of commercial board of thickness				
6	Hand rails with supporting bars				

	made of hardwood.				
7	Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124779 dated 25.04.2022			
Name of the item :		Wheel Chair (Manual)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
	Width: 21.5" (17" seat); 23.5" (19 seat)				
	Length/Depth: 24"				
	Weight Capacity: 180 kg.				
	Seat Width: 17" or 19"				
	Seat Depth: 16"				
	Seat to Floor Height: 19".				
	Back Height: 17"				
	Arm rest: Removable				
	Front Riggings: Swing-away aluminium Footrests				
	5 cm 50PU density foam cushioned				

	top and back covered with leathered Rexene of 2mm thickness				
	Rear Axle: Single Position 12mm				
	All the Stainless Steel should be 304 grade/ 16 gauge				
	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
	Specifications for Pediatric Wheelchair				
	Aluminum Special Functional Epoxy Detachable Arm Rest & Foot Rest.				
	Seat & Back Upholstery made of colored Leatherette				
	8" Front Wheel & 24" Rear Wheel				
	Seat Width 38cms & Overall width 58cms				
	Adjustable Arm Rest				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124746 dated 25.04.2022			
Name of the item :		Motorized Wheel Chair			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Load capacity : 100 Kg (minimum)				
2	Speed : Up to 8 km/hr				
3	Motor power : 270-320 Watt				
4	Motor speed : 4700-5300 rpm				
5	Brake : Electromagnetic				
6	Gradeability : 10 degree (minimum)				
7	Ground Clearance : 7 cm (minimum)				
8	Drive Range : 10 km (minimum)				

9	Trun Circle Radius : 60 cm (max)				
10	Battery : 20 volt 24ah maintenance free				
11	Total Dimension :				
a	Total Length- 100 cm				
b	Total Width≤60 cm				
c	Total Height ≤100 CM				
12	Seat Dimension :				
a	Depth =40 cm				
b	Width =50 cm				
c	Back Height =40 cm				
d	Back Width =50 cm				
13	Arm Support Width : 5 cm (minimum , height of arm support should be adjustable)				
14	Foot Support : 20 cm in length (minimum ,height of support should be adjustable)				
15	It should be able take signal thought joy stick mounted in right arm support signals from other Means through wired .				
16	Should have removable arm rest & Foldable foot support .				
17	Should have reclining mode .				
18	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124708 dated 25.04.2022			
Name of the item :		Hip, Knee, ankle CPM			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks

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		Comments			
1	Unit should be able to work on adult and pediatric				
2	Unit should have facility automatically increasing the programmed flexion angle by very hour up to 5 ° per 24 hour period of time				
3	Unit should have facility to work more in working ROM mimicking oscillation with hand..				
4	Unit should accelerate quicker through the non-working ROM				
5	Unit should have facility that when the patient's threshold for pain is reached, allows the unit to continue working the affected limb but at a reduced flexion angle limit.				
6	Force Reversal: Safety allowing the therapist to set an amount of passive force without causing damage to the surgery or unnecessary pain i.e. 16 – 34 kgs				
7	Should have following:				
8	extension (-10°) to (120°)				
9	Speed Range : 32 degree min to 145 degree min				
10	Should have automatic pause in between				
11	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
12	Added: - All three movement in single unit. Ankle movement 20 degree to – 30 degree				

<u>COMPLIANCE STATEMENT</u>	
Bid No :	GEM/2022/B/2124681 dated 25.04.2022
Name of the item :	Shoulder CPM

Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
	The Shoulder CPM should have following features:				
1	Control should be either from main unit or Hand held pendant				
2	Storage card/Internal memory for storing programmed values				
3	Universal left/right design for both arm activity.				
4	Anatomically correct adjustment				
5	Motor Control: on/off				
6	Reverse-on-load — unit should switch to the opposite direction when patient resistance increases the target set value.				
7	Patient compliance meter should calculates the cumulative patient use time				
8	Warm-up mode — the unit should recognizes the start and stop angles and midpoint. From that point, motion should initiated 3 degrees from all angles until full				
9	ROM is achieved.				
	Pauses: 0-20 seconds				
	Speed: 0-100%				
	Timer: 0-250 minutes				
10	The Shoulder CPM should allows the following motions of the shoulder joint:				
a	Adduction/Abduction 0°- 30° - 175°				
b	Internal/External Rotation 90°- 0° - 90°				
c	Elevation (Flexion) with 60° - 90° flexion of the elbow 30° - 175°				
d	Ante/Retroversion (horizontal adduction/abduction) set manually 0° - 125°				
11	Mains Power: 230V, 50/60 Hz,				
	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered				

	with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body			
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COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124598 dated 25.04.2022			
Name of the item :		Ultrasonic Therapy Machine (UST)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Ultrasonic Therapy — Digital				
2	Pulsed and continuous therapy operation				
3	Digital control circuitary / Digital timer 0 to 30 minutes or more with digital display				
4	Output power 15W (Continuous), 21W (Pulsed) or upto 2.5 watts /cm2, which				
5	Output frequency 1 MHz				
6	Pulse ratio:1:2, 1:4, 1:8, 1:16				
7	Pulse frequency 8 Hz, & 16 Hz				
8	Display- Seven segment display				
9	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT	
Bid No :	GEM/2022/B/2124579 dated 25.04.2022
Name of the item :	Cryotherapy

Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Unit should have chilling coils .				
2	Unit should be equipped with heavy duty compressor for fast cooling and it should cool faster even if lid will be open frequently.				
3	Unit must have Closed-cell foam insulation for energy efficiency.				
4	Should have facility for easy cleaning and defrosting				
5	Unit should be made up of stainless steel				
6	Unit should provide casters facility				
7	Unit should provide Temperature Range from -12 degree C to -6 degreeC				
8	Safety Class : Type B				
9	Safety Tests : Safety Tests: EN 60601-1 should provide certificate.				
10	Unit should provide with 6 Standard size (28 cm x 36 cm) and 6 Half size (19 cm x 28 cm) coldpacks with non-toxic gel and should be latex free.				
11	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

<u>COMPLIANCE STATEMENT</u>	
Bid No :	GEM/2022/B/2124568 dated 25.04.2022
Name of the item :	Short Wave Diathermy (High Power)
Name of the Bidder :	M/s.
Name of the Manufacturer of quoted item :	M/s.

Country of Origin of quoted item :					
Model Quoted:					
SI. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
SI NO.					
1	Shortwave Diathermy power output 450-500W with continuous and pulsed mode				
2	Standard accessories: Pad Electrodes				
3	High power medical diathermy incorporating a high power transmitting oscillator valve and solid state rectifier.				
4	Cooling fan- available				
5	RF power source Vacuum generating valve				
6	Output frequency 27.12 MHz				
7	Wavelength: 11 meters				
8	Operative Voltage : 230 V, AC 50Hz.				
9	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
10	Added Para – User defined/pre-programmed protocols				

<u>COMPLIANCE STATEMENT</u>					
Bid No :		GEM/2022/B/2124549 dated 25.04.2022			
Name of the item :		Hydro collator or Moist Heat Therapy Unit			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
SI. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
1	Minimum Size : L x 12" W x 18" Depth				

2	Stainless steel heavy duty gauge tank well insulated, temperature control, auto cut-off, hot packs for back, knees and shoulder, Side hooks for Packs				
3	Tap for water drainage				
4	Mounted on high quality castor wheels				
5	Handles for carrying the unit from one place to another				
6	Fitted with 1000 W heating element				
7	Tank capacity should be 45 -49 ltr				
8	Temp range should be from 72 to 74 deg C				
9	Should have additional Thermal cut out at temp 82 to 85 deg C				
10	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124500 dated 25.04.2022			
Name of the item :		PARAFFIN WAX BATH			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
a	Internal wax tank minimum size will be around : 22x16x12 inches.				
b	Internal wax tank should be made of stainless steel sheet.				
c	The top has a metallic cover and the edges of the bath have a laminated covered wooden rim, all around the top				
d	Should have castors for easy mobility.				
e	Works on 220V A.C. , provided with				

	one special wax immersion heater and thermostat to control temperature from 0 to 100 deg.Cent.				
f	Should provide with 10kg wax				
g	Added Para : Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

<u>COMPLIANCE STATEMENT</u>					
Bid No :		GEM/2022/B/2124464 dated 25.04.2022			
Name of the item :		Transcutaneous Electric Nerve Stimulation (TENS)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES - Give Comments	Remarks
1	Output Channel : Min. 4 channel				
2	Input voltage : 220v Ac / 50Hz				
3	Intensity : 99 mA				
4	Frequency : 2, 20,40, 80,120 Hz				
5	Pulse Duration : Normal				
6	Dimension Normal : (245x220x88) (LxWxH) mm				
7	Timer : 0 to 99 minutes				
8	Safety : Isolated power output				
9	Various modes, including continuous, burst, pulsed, width and frequency modulation.				

10	Should be portable and light weight.				
11	Should be provided with following accessories:				
a	- 8 rubber electrodes				
b	- 4 output cables				
c	- 8 straps				
12	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

COMPLIANCE STATEMENT					
Bid No :		GEM/2022/B/2124446 dated 25.04.2022			
Name of the item :		TRACTION (Electronic Traction system for cervical and lumber traction)			
Name of the Bidder :		M/s.			
Name of the Manufacturer of quoted item :		M/s.			
Country of Origin of quoted item :					
Model Quoted:					
Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES -Give Comments	Remarks
a	An accurate and sturdy intermittent traction machine				
b	Dimension (L x H x D) : 325mm x 290mm x 310mm				
c	Weight (approximately) : 10-15 kg				
d	Operating Voltage : 220V AC, 50 Hz				
e	Absorption : 37 Watts- Max				
f	Fuses : 500 mA				

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g	Room temperature : 10 degree to 40 degree Celsius				
h	Moisture : 10% to 80%				
i	Treatment Mode : Static/ Intermittent				
j	Traction Force : 5 to 45 Kg				
k	Cervical : 5 to 15 Kg				
l	Lumbar : 23 to 45 kg				
m	Hold Time : 10,20,40, 60, 80 sec with LED indicator				
n	Rest time : 1,5,10,15, 20 sec with LED indicator				
o	Timer : 01 to 99 minutes programmable				
p.	Patient safety : available				
q	Solid moulded aluminium gear box assembly and high power sturdy motor.				
r	The treatment time is electronically controlled and displayed digitally.				
s.	At the end of treatment time the alarm comes up, traction stops automatically and releases the patient.				
t.	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				
u.	Added Para – Sturdy adjustable height traction table imported should be supplied				

<u>COMPLIANCE STATEMENT</u>	-
Bid No :	GEM/2022/B/2124432 dated 25.04.2022
Name of the item :	Portable Combination Therapy
Name of the Bidder :	M/s.
Name of the Manufacturer of quoted item :	M/s.
Country of Origin of quoted item :	
Model Quoted:	

Sl. No	Technical Specification	Compliance to the Tender Specification- Give Comments	Data Sheet Para & Page No	Deviation if any(Y/N), if YES - Give Comments	Remarks
1	A single unit consist of Electrotherapy Current and 1 & 3Mhz Ultrasound .				
2	Should have inbuilt Clinical Library for Electro Therapy and Ultrasound Modalities				
3	Should have facility to run three treatments simultaneously with individual parameters				
4	In combination mode , it should deliver selected current from the ultrasound applicator along with ultrasound waves				
5	Equipment should have Graphic LCD screen with minimum of 5.7 inch diagonal length				
6	Equipment should have S-D curve facility where all reading should appear in tabulation				
	Unit should have following minimum current with given specifications of the parameters :				
	4 Pole with Vector				
	2-Pole				
	I-Galvanic with frequency upto 100 Hz and width from 0.01 to 300 mSec				
	Russian with Ramp ON / OFF				
	TENS with selection of Symmetrical and Asymmetrical biphasic output				
	Iontophoresis				
	NMES with Single , Reciprocal and Co-Contraction modes				
	Ultrasound Therapy should deliver 1 Mhz or 3 Mhz from the single applicator .				
	Ultrasound should have facility to adjust following parameters				
	Timer : 1 - 90 min				
	Duty Cycles : Pulsed : 10%, 20%, 50%				
	Continuous : 100%				
	Rate : 16, 48, and 100 Hz				
	Frequency : 1MHz, 3MHz				

	Intensity : 0 to 2.5 W/cm ²				
	System should supply with two set of output cable, 4 rubber electrodes, 1 packet of pre-jelled sticking electrode, point electrode.				
	Manufacturer should have ISO 13485:2016 certification issued from : Any Certification Bodies registered with NABCB under Medical Devices Quality Management System OR Any notified body registered with CDSCO OR Any 4-digit CE notified body				

All other contents of the Bid Document including terms & conditions remain unaltered.

Note:

- I. Prospective Bidders are also advised to check the website regularly prior to the closing date and time of online submission of bids**