




## Waiver of Registration Committee - Device 13/01/2024

No	Date of Submission	NMRA Ref: Number	Item	Qty	Invoice / Tender Number	Invoice Value	Applicant	Manufacturer / Supplier	Reason for WOR	Remarks	WOR Committee Recommendation
1	24/11/2023	MD/186 3/11/2023	Intra Corporeal Pneumatic Lithotripter with Accessories and Spare Parts (Brand : Lithomed - Digital)	01 bOX (03 pCS)	55, date: 20/05/2021	USD 3900.00	R&D Intertrades (PTE) Limited	ARK Meditech Systems - India	For UHKDU	Registered product and expired on 2022. Not renewed the registration.	Not recommended and advised to renew the registration.
2	05/12/2023	MD/187 9/12/2023	Hospital Beds	2	19122023-1, date: 15/11/2023	SGD 200	Ven. Ratanasiri Thero, Metta Buddhist Centre	Asiri Trading Pte.Ltd - Singapore	N/A	-	Pending decision. Advised to request distribution list.
3	07/12/2023	MD/188 1/12/2023	Pharmacy Refrigerator	1	HRP-001-MBPL-2023, date: 10/10/2023	USD 3400.00	Microtech Biological (Pvt) Ltd	Qingdao Haier Biomedical Co.Ltd - China	For Central Insemination Station, Department of Animal Production and Health - Kundasale	Manufacturer registered under NMRA with another local agent.	Not recommended and advised to register the product.
4	21/12/2023	MD/190 6/12/2023	Ultra Low temperature freezer	2	HW231107LKA001, date: 07/11/2023	USD 260.00	Microtech Biological (Pvt) Ltd	Anhui Zhongke Duling Commercial Appliance Co.Ltd - China	For Department of Agriculture, Horticultural Corp Research and Development Institute - Gannoruwa	Manufacturer not registered under NMRA.	Not recommended and advised to register the product.

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
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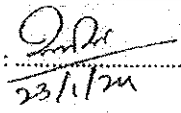
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5	05/12/2023	MD/188 3/12/2023	Standard Q Leptospira IgM/IgG Test	200	SMS231 107-1, date: 07/11/2023	USD 13,500. 00	George Steuart Health (Pvt) Ltd	SD Biosensor Inc - Kore	For Several Government Institution	Registered manufacturer under NMRA. SIL applied.	Not recommended and advised to register the product.
6	05/12/2023	MD/188 7/12/2023	Spectra Optia Exchange Set / Spectra Optia IDL Set	36EA +150E A	9500969 31, date: 11/10/2023	USD 24,180. 00	Hemas Surgicals & Diagnostics (Pvt) Ltd	Terumo BCT Asia Pte.Ltd - Singapore	For National Blood Transfusion Service	Previously registered product and applied due to the manufacturing site change. New file submitted to NMRA for registration.	Not recommended. Advised to expedite the registration.
7	01/01/2024	MD/191 5/01/2024	Control, Calibrators, Accessories and Spare Parts for Hematology Analyzer	As per the invoic es	10045488, date: 29/09/2023, 10048801, date: 27/12/2023	USD 758.00 + USD 57,594. 32	Hemas Surgicals & Diagnostics (Pvt) Ltd	Nihon Kohden - Japan	For Sri Lanka Air Force	-	Not recommended. Advised to apply for certificate amendment.
8	21/12/2023	MD/189 7/12/2023	Horse Serum (Brand: Sigma)	2	8206451 278, date: 15/11/2023	EUR 100.40	Neochem Lifescience (Pvt) Ltd	Sigma Aldrich - Germany	For Department of Parasitology, Faculty of Medicine, University of Colombo	For a research Purpose. ERC approval available.	Recommended only for this consignment.
9	05/12/2023	MD/192 2/01/2024	Acrylamide Molecular Biology Reagent (Brand: Sigma)	1	8206451 278, date: 15/11/2023	EUR 134.00	Neochem Lifescience (Pvt) ILtd	Sigma Aldrich - Germany	For Department of Biochemistry & Clinical Chemistry, Faculty of Medicine, University of Kelaniya	For a research Purpose.	Recommended only for this consignment.

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10	21/12/2023	MD/190 3/12/2023	College of American Pathologist (CAP) Proficiency Testing Program	As per the invoice	CAP No: 902147901, Bill No: 902147901, Quote No: 461432, date: 23/10/2023	USD 76,109.00	Lanka Hospital Diagnostics (Pvt) Ltd	College of American Pathologist - USA	CAP Programm		Recommended only for this consignment.
11	21/12/2023	MD/190 4/12/2023	Non-Absorbent Cotton Wool / Dissecting Forceps	As per the invoice	EXM-027, date: 06/09/2023	As per the invoice	Organic Trading (Pvt) Ltd	Anant Surgical Industries - India	For University of Ruhuna, Rajarata University of Sri Lanka, University of Sri Jayawardenepura, Eastern University - Sri Lanka	Registered suppliers available.	Not recommended and advised to register the product.
12	21/12/2023	MD/190 7/12/2023	Lyophilized Human Serum, Stimulated Whole Blood	As per the invoice	LKA2023 1024133 237, date: 06/10/2023	USD 50.00	Biomedite (Pvt) Ltd	For Oneworld Accuracy Inc - Canada	External Quality Assurance Programme	For Association of Clinical Biochemistry.	Recommended only for this consignment.
13	21/12/2023	MD/190 8/12/2023	Human Serum, Stimulated Whole Blood, Aqueous Solution, Stabilized Liquid hemolysate, Liquid human plasma, Stimulated Whole Blood, Liquid human plasma, Formalin Preserved fecal suspension.	As per the invoice	LKA2023 1018185 027, date: 15/09/2023	USD 50.00	Biomedite (Pvt) Ltd	For Oneworld Accuracy Inc - Canada	External Quality Assurance Programme	For Association of Clinical Biochemistry.	Recommended only for this consignment.

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14	21/12/2023	MD/190 9/12/2023	EGFR Gene Mutations Detection Kit, K-ras Gene Mutations Detection Kit, B-raf Gene Mutations Detection Kit	4	Spacegen nIS20230 91501, date: 15/09/2023	US\$ 2,220.00	Biomedite (Pvt) Ltd	Xiamen Spacegen - China	For National Hospital - Kandy	Request from molecular diagnostic unit NH - Kandy. Applied for manufacturing site registration.	Recommended only for this consignment.
15	29/12/2023	MD/191 2/01/2024	Rescue Pak Extended Care (Brand : DAN)	1	SH10000 115, date: 09/11/2023	USD 1,093.21	Mr. Yohan Abeysekara	Divers Alert Network (DAN) - USA	For Sri Lanka Navy Headquarters	Request to clear emergency rescue pack for divers including oxygen cylinder and masks.	Recommended only for this consignment.
16	29/12/2023	MD/191 3/01/2024	ImmunoCap Reagents (Brand: Phadia)	As per the invoice	PI2023-12-13 v.2 - 19/12/2023, PI2023-10-23, date: 02/11/2023	USD 4,417.98 + USD 12,375.97	Highchem R Ceylon Company (Pvt) Ltd	PhadiaAB - Sweden	For Medical Research Institute, University of Sri Jayawardenapura	Previously registered and expired product on 2022.	Not recommended. Advised to apply for registration.
17	29/12/2023	MD/191 4/01/2024	6% Hydrogen Peroxide (Brand: NOCOTECH)	40	2311026 2, date: 28/11/2023	\$3,863.54	Global Healthcare Innovations (Pvt) Ltd	Oxypharm - France	For Several Private and Government Institutions		Not recommended. Committee suggested to revisit the tender decision. Advised to buy from registered sources.

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18	30/11/2023	MD/186 9/11/2023	Alginate Impression powder	1800	ZG2023- D0718, date: 14/10/2023	\$3,069. 00	Oseth Pharmaceuti cals	Zogear Industries Co.Ltd - China	For Health System Enhancement Project	Recommendation from consultant in restorative dentistry available.	Not recommended. Advised to expedite the registration.
19	30/11/2023	MD/187 0/11/2023	GP Point 15 - 40	3000	LKA-SL- 2023082 5, date: 20/09/2023	\$3,485. 00	Oseth Pharmaceuti cals	Huizhou Videya Technology Co.Ltd - China	For Health System Enhancement Project	Recommendation from consultant in restorative dentistry available.	Recommended only for this consignment.
20	15/11/2023	MD/183 5/11/2023	Etching Gel (37% Phosphoric Acid) (Eco-Etch Refill)	9483+ 9483	01/IVO/A BC/3/202 3-24, date: 24/10/2023 02/IVO/A BC/3/202 3-24, date: 24/10/2023	USD 161,211 .00 + USD 161,211 .00	ABC Phama Services Pvt) Ltd	Ivoclar Vivadent AG Schaan, Liechtenstein	For Health System Response Project - AIIB (Health System Enhancement Project)	Recommendation from consultant in restorative dentistry available.	Recommended only for this consignment. Committee advised to submit the dossier for registration within 3 months.

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21	13/11/2023	MD/184 9/11/2023	1. Human Serum Albumin nano sized colloid 500 micrograms (Brand: Nano-Scan (Tc-MR-7))	Kit/6 vials	2023SZA /54046/U SD, date: 18/10/2023	\$6,828.00	Sunpro Healthcare (Pvt) Ltd	Medi-Radiopharma Ltd - Hungary	For Nuclear Medicine Department, The Lanka Hospital Co. PIC	Not recommended and advised to register the product.
			2. Sestamibi Tetrafluoroborate 0.5mg (Brand Name: Medi-Mibi 500 micrograms (Tc-MR-1))							
			3. Meso-2-3-dimercapto Succinic Acid (DMSA) 3.0mg (Brand: Mercapton (DMSA) (Tc-MR-13),)							
			4. Acidum-Diaethylenetriamino-pentaaceticum (DTPA) 10.0mg (Brand Name: Renon (DTPA) (Tc-MR-11),							
			5. Human Serum Albumin Macroaggregate 2.0mg (Brand Name: Macr-Albumon (MAA)(Tc-MR-2),							
			6. Methylene diphosphonic Acid (MDP) 5.0mg (Brand Name: Skeleton (MDP) (Tc-MR-10)							

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22	11/12/2023	MD/189 4/12/2023	ELISA Kits		ED20231 027LKA, date: 01/12/2023	\$1,197. 50	Avon Pharmo Chem (Pvt) Ltd	Wuhan E Labascince Biotechnology Co.Ltd - China	For National Aquatic Resources Research & Development Agency (Research Purpose)		Not recommended and advised to register the product.
23	01/01/2024	MD/192 0/01/2023	Bioline Filariasis Test Strips	200	1350405 31, date: 11/12/2023	USD 13,189. 18	International Organization for Migration	Abbot Rapid DX International Limited - Ireland	Donation		Not recommended. Advised to withhold and discuss with IOM.
24	10/01/2024	MD/193 0/01/2024	Rigid Strapping Tape	140	GSH 146/2023 24/10/2023	USD 14,467. 60	George Steuart Health (Pvt) Ltd	Pharmacare Limited - Thailand	For institute of Sports Medicine		Not recommended and advised to register the product.
25	12/01/2024	MD/193 3/01/2024	Cell and tissue Freezing bag 14x30cm	200	56091 (PO: EP/OG/0 1/2023), date: 14/11/2023	\$2,600. 00	Emar Pharma (Pvt) Ltd	Orgien Biomedical Inc - USA	For Lady Ridgway Hospital for Children		Recommended only for this consignment. Advised NMRA to categorize this product under listed items.
26	12/01/2024	MD/193 6/01/2024	PR 4100 Absorbance Microplate Reader	As per the invoic e	1007277 797, date: 23/11/2023	USD 9921.00	Emar Pharma (Pvt) Ltd	Bop-Rad - France	For NBTS		Recommended only for this consignment Subject to submission of variation documents for site change.


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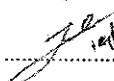
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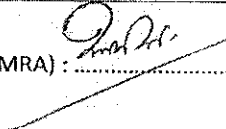
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27	12/01/2024	MD/193 7/01/2024	Viasure H. influenzae, N. Meningitidis & S. pneumonia Real Time PCR Detection Kit	1	PROF23/2301721, date: 27/12/2023	EUR 772.50	Microtech Biological (Pvt) Ltd	Certest Biotec S.L - Spain	For Medical Research Institute	-	Recommended only for this consignment.
28	12/01/2024	MD/193 9/01/2024	Pharmacy Refrigerator (Model MPC-5V1006), Pharmacy Refrigerator (Model MPC-5V656), Combined refrigerator and freezer	1+1+1	HW231222LKA001, date: 22/12/2023	USD 4800.00	Microtech Biological (Pvt) Ltd	Anhui Zhongke Duling Commercial Appliance Co.Ltd - China	For Open University of Sri Lanka	-	Not recommended and advised to register the product.
29	13/11/2023	MD/182 3/11/2023	Non-Woven adhesive Bandage and Kinesiology Type	17552	23/66086, date: 23/08/2023	USD 6456.69	CIC Holdings PLC	Suzhou Sunmed Co.ltd - China	-	-	Recommended only for this consignment Subject to submission of dossier.
30	05/12/2023	MD/187 7/12/2023	Lubricant Water Based 4.3ml	100,000	00007749, date: 10/08/2023	USD 4,761.00	National STD/AIDS Control Programme	Karex Industries SDN BHD - Malaysia	From United Nations Population Fund to National STD/AIDS Control Programme	Donation	Recommended only for this consignment.
31	05/12/2023	MD/187 8/12/2023	S0001317 Centrifuge DM0636 complete with package 4 accessories Standard / Microscope, trinocular/camera, LED Standard	06+06	72023848, date: 11/10/2023	EUR 44915.46	Ministry of Health	Svizera Europe B.V - The Netherland	From United Nations Population Fund to government of Sri Lanka	Donation	Recommended only for this consignment. Advised to submit relevant documents and end user list.

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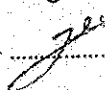


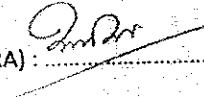
32	14/12/2023	MD/188 8/12/2023	Maternity Kit	950	23/0453B date: 03/11/2023	USD 50,270. 50	Ministry of Health	Ram Dis Ticaret A.S - Turkey	Donation	Donation	Recommended only for this consignment.
33	14/12/2023	MD/188 9/12/2023	1. Digital Dry Baths/Block Heaters , Thermo Scientific / 88870004+Block, 1.5ml and 2.0ml, Thermo Scientific / 88870113, 2. EDTA 10 MI, BD/367525	1+1	2032186 34, date: 15/08/2023	INR 46538.7 5	Ministry of Health	World Health Organization, Global Procurement and Logistics - Malaysia	Donation	Donation	Recommended only for this consignment.
34	12/12/2023	MD/189 0/12/2023	Glove Examination, long cuff, latex, non-sterile, powder free, size S/M/L	4000+ 15000 +4000	2033354 74, date: 11/12/2023	USD 161,000 .00	Ministry of Health	World Health Organization, Global Procurement and Logistics - Malaysia	Donation	Donation	Recommended only for this consignment.
35	08/12/2023	MD/189 3/12/2023	Hospital Equipments	As Per the invoice	03978, date: 12/10/2023	A 513.50	Ministry of Health (Lak Saviya Foundation Australia Incorporated)	Lak Saviya Foundation - Australia	Donation	Donation	Recommended only for this consignment. Advised to submit delivery note from relevant institution.
36	18/12/2023	MD/189 5/12/2023	Striker Lucas 3 Chest Compression Therapy System Machine	4	63774, date: 12/12/2023	\$81,768 .00	Ministry of Health	B2B Commodity Distributors LLC - USA	Donation	Donation	Recommended only for this consignment.
37	19/12/2023	MD/189 6/12/2023	Dengue IgG capture Elisa Kit/SuperScript III Platinum One Step qRTPCR	6+10 (Pack ages 2)	2032542 73 (AAA/2023), 12/12/2023	INR 181750 0.00	Ministry of Health	World Health organization, South-East Asia - India	Donation	Donation	Recommended only for this consignment.

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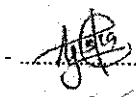
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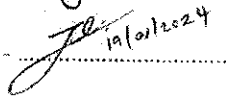
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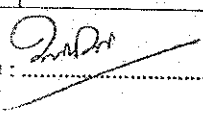
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38	01/01/2024	MD/191 9/01/2024	Medical Devices/Equipments	As per the invoice	CI23006 25, date: 19/12/2023	USD 14,238. 00	Ministry of Health	Imres B.V - Netherland	Donation	From United Nations Children's Fund.	Recommended only for this consignment.
39	01/01/2024	MD/192 1/01/2024	GXHIV-VL-CE-10 KIT,GX,10- TEST,HIV- 1,QUANT,CE-IVD	100	9001510 078	\$14,900 .00	Ministry of Health	Cepheid HBDC SAS - Netherland	Donation to STD	Donation	Recommended only for this consignment.
40	04/01/2024	MD/192 7/01/2024	Dialyzer Dialysis Fluids	60 + 40	00520, date: 22/12/2023	\$280.00	Ministry of Health	Padma Enterprises - Nagpur	Donation	Request from LRH available.	Recommended only for this consignment.
41	04/01/2023	MD/192 8/01/2024	Measles Modules	Packa ges 06	157/2023 (PO: 2030609 73), date: 27/12/2023	USD 5340.46	Ministry of Health	World Health Organization, South-East Asia - India	Donation	Donation	Recommended only for this consignment.
42	15/11/2023	MD/182 9/11/2023	Vaccine Refrigerator (With Voltage Stabilizer / Spare Parts	50 + 5	SWW901 5945, date: 14/11/2023	USD 70,050. 00	Ministry of Health	Qingdao Haier Biomedical Co.ltd - China	Donation from United Nations International Children's Emergency Fund to government of Sri Lanka	Donation	Recommended only for this consignment.
43	13/10/2023	MD/178 7/10/2023	Audio Meters	04 Boxes	KY/00/31	\$880.00	Rotary Club of Kandy	Gunter Volkman - Denmark	Donation to Rotary Club of Kandy	Donation	Recommended only for this consignment. Advised to submit list of beneficiaries.
44	06/12/2023		Levoplant Contraceptive Implant Eng/Fr	40000 Piece	PO: 7003562 6, date: 01/08/2023	USD 286,000 .00	Ministry of Health	WomanCare Global Trading CIC - London	Donation (Extention)	Donation	Recommended only for this consignment.

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45	03/01/2024		Male Condom Practice Model and Newborn, CPR, advanced care simulator	10 + 10	3058815, date: 06/09/2023	USD 4376.60	Ministry of Health	Fleischhacker GmbH & CoKG - Schwerte	Donation (Extention)	Donation	Recommended only for this consignment.
46	06/12/2023		EIA Dengue (Platelia-72830) NS1 Ag ser/pl.w/0 acc (96kits) and data logger	8+1	203144038, date: 16/05/2023	EUR 4691.00	Ministry of Health	World Health organization, Global Procurement and Logistics - Malaysia	Donation (Extention)	Donation	Recommended. Extended.
47	06/12/2023		DW-30L508 Freezer	1	202934199, date: 03/06/2023	USD 1,650.00	Ministry of Health	World Health organization, Global Procurement and Logistics - Malaysia	Donation (Extention)	Donation	Recommended. Extended.
48	05/12/2023	MD/188 5/12/2023	PCR Halogen Lamp	1	EXP-PI 2023/176, date: 31/03/2023	216.95	Medical Research Institute	Fleischhacker GmbH & Co. KG - Schwerte	Donation to MRI	Donation	Recommended only for this consignment.
49	05/12/2023	MD/188 6/12/2023	Diagnostic Kits (Perishable) (Measles 1gm Kits, Rubella 1gm kits, Micro-Immune 1gm Measles Kits, Micro-Immune 1gm Rubella Kits, Measles 1gG Kits, Rubella 1gG Kits)	01 Package	134/2023 (PO: 2030751 49+2031 93380+2 0310910 3)	INR 90,000.00	Medical Research Institute	World Health organization, South-East Asia - India	Donation to MRI	Donation	Recommended only for this consignment.

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50	01/01/2024	MD/191 6/01/2024	Beta Lactamases Sricks 30 strips x 3 = 90	1	094/2023 (PO: 2031179 03), date: 28/08/20 23	INR 25,200. 00	Medical Research Institute	World Health Organization, South East Asia - India	Donation to MRI	Donation	Recommended only for this consignment.
51	22/11/2023	MD/185 4/11/2023	Medical Supplies (Perishable)	3	105/2023 (PO:2032 05258), date: 06/09/20 23	INR 39,498. 00	Medical research Institute	World Health Organization, South-East Asia - India	Donation	Donation	Recommended only for this consignment.
52	08/01/2024	MD/192 3/01/2024	IRR/CDC Influenza Virus Real Time PCR Reagents	27	CINV000 76806, date: 19/12/20 23	\$9.50	Medical Research Institute	ATCC - USA	Donation to MRI	Donation	Recommended only for this consignment.
53	08/01/2024	MD/192 4/01/2024	IRR/CDC Influenza Virus Real Time PCR Reagents	1	CINV000 76807, date: 19/12/20 23	\$0.50	Medical Research Institute	ATCC - USA	Donation to MRI	Donation	Recommended only for this consignment.
54	08/01/2024	MD/192 5/01/2024	Medical Supplies (Vancomycin E Strips, Pencillin E strip, Cefotaxime E strips, Ciprofloxin E strips 0.03, Levofloxacin E strips, Optochin 5ug disks)	6 (02 Packa ges)	Exp- 103/2023 (PO:2031 17909), date: 28/08/20 23	INR 39,498. 00	Medical Research Institute	World Health Organization, South-East Asia - India	Donation to MRI	Donation	Recommended only for this consignment.

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*[Signature]* 19/01/2024

55	08/01/2024	MD/192 6/01/2024	Beta Lactamases	1	106/2023 (PO:2032 05275), date: 05/09/2023	INR 25,200. 00	Medical Research Institute	World Health Organization, South-East Asia - India	Donation to MRI	Donation	Recommended only for this consignment.
56	07/12/2023	MD/188 0/12/2023	CellQART 24-Well Insert 3.0um PET clear	1	AU23146 5, date:29.0 9.2023	172.95	Prof. Prasanna Galhena, Director, Institute of Biochemistry, Molecular Biology & Biotechnolog y, University of Colombo (IBMBB)	SABEU GmbH & Co. KG - Germany	For University of Colombo, For research Purpose	Donation	Recommended only for this consignment.
57	11/12/2023	MD/189 1/12/2023	Articulators - Simple Hinge (Stainless Steel)	100	MI-2451, date: 01/09/2023	US \$ 1025.00	Faculty of Dental Sciences, University of Peradeniya	Moin International - Pakistan	Manual Articular for Laboratory use	Donation	Not recommended. Committee advised to categorize under listed items.
58	11/12/2023	MD/189 2/12/2023	Gracy Currettee Set of 7 Pcs	10	MI- 210458	US \$ 185.00	Faculty of Dental Sciences, University of Peradeniya	Moin International - Pakistan	For Teaching Purpose	Donation	Recommended only for this consignment.
59	01/01/2024	MD/191 8/01/2024	Insulin Delivery Pen Devices	1465	8021010 5-Sri Lanka, date: 13/11/2023	\$ 11.72	Sri Lanka College of Endocrinolog ists	Lilly, Eli & Co	Donation	Donation	Recommended only for this consignment.

Prepared By : Mrs. N.B. Ayesha Udayangani

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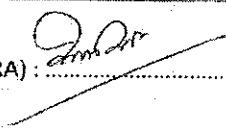
CEO (NMRA) :

Dr. Saveen Fernando  
MBBS, MSc, MD  
Chief Executive Officer  
National Medicines Regulatory Authority  
No. 120, Norris Canal Road,  
Colombo 10.

## Waiver of Registration Committee - Device 13/01/2024 - S.P.C

No	Date of Submission	NMR A Ref: Number	Item	Qty	Invoice / Tender Number	Invoice Value	Applicant	Manufacturer/ Supplier	Reason for WOR	Remarks	WOR Committee Recommendation
1	22/12/2023	MD/18 99/12/ 2023	Cardioplegia Delivery Set, Haemoconcentrator Set (Brand: BL)	900+1 50	LP/DHS/ RSS/RQ/ 245/717 DR/2021, date: 30/11/20 23	LKR 14,700, 000.00	Technomedics International (Pvt) Ltd	BL Lifescience (Pvt) Ltd - India	SPC tender	Other registered sources available.	Not recommended. WOR not considered as there are other - registered sources quoted.
2	22/12/2023	MD/19 00/12/ 2023	PAD WI-FI 64GB - IPAD GEN 9 (Model A2602)	4	DHS/SU S/WW/64 /215DP/2 022, date: 30/06/20 23 (CRM_11 2023_75, date: 16/11/20 23)	USD 1,582.0 0	Medtrac (Pvt) Ltd	Medtronic International Ltd - Singapore	SPC tender	<ul style="list-style-type: none"> <li>• I pads for Medtronic "Care Link Smart Sync" device manager used in ICD applications.</li> </ul>	Not recommended. Advice to apply for amend certificate for inclusion.
3	30/10/2023	MD/18 06/10/ 2023	Trulene 6-0 60CM 3/8 Cricle RB 8mm	700 NOS	DHS/RS S/RQ/22 4/663NS L/21, date: 23/05/20 23	US\$ 1,610.0 0	Synergy Life Solutions (Pvt) Ltd	M/S. Healthium Meditech Limited - India	SPC Tender	<ul style="list-style-type: none"> <li>• Manufacturer registered with NMRA.</li> <li>• Not applied for registration.</li> <li>• Agency Transfer from Dowell.</li> </ul>	Not recommended. Advised to apply for registration.

Prepared By : Mrs. N.B. Ayesha Udayangani -  18/01/2024

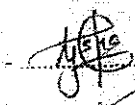
CEO (NMRA) : 

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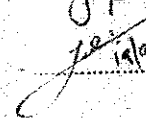
**Dr. Sareen Samage**  
 MBBS, MSc, MD  
 Chief Executive Officer  
 National Medicines Regulatory Authority  
 No. 120, Norris Canal Road,  
 Colombo 10.

4	23/10/2023	MD/18 02/10/ 2023	Cervical Wooden Spatula Ayre type (or Similar)	350,0 00 NOS	LP/DHS/ RSS/RQ/ 293/705 DR/2021, date: 09/10/20 23	LKR 4,987,5 00.00	Marco Lab (Pvt) Ltd	Jiangsu Hanheng Medical Technology Co.Ltd - China	SPC Tender	<p>Manufacturer or Local Agent not registered with NMRA.</p> <p>Submitted to WOR Committee held on 14/11/2023 and Decision was Recommended with condition Subject to submission of dossier. Again Submitted to WOR Committee held on 05/12/2023 and Decision was Advised to either procure from registered sources or submit the dossier for product registration Subject to submission of Dossier for product registration.</p>	<p>Not recommended. Advised to Expedite the registration.</p>
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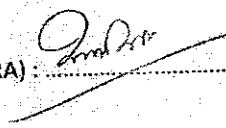
Prepared By : Mrs. N.B. Ayesha Udayangani

 18/01/2024

Checked By : Ms. H.M.O.I. Priyashantha

 19/01/2024


CEO (NMRA)



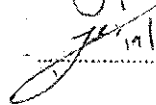
Dr. Saveen Samage  
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5	19/12/2023	MD/18 98/12/ 2023	HLA transport Reagents	As per the invoic e	LP/DHS/ RL/EP/1/ 012WAC/ 23, date: 18/07/20 23, LP/DHS/ RL/EP/2/ 013NK/2 023, date: 01/09/20 23	LKR 213,560 ,290.29 + LKR 190,943 ,900.03	Premium International (Pvt) Ltd	Immucor Inc - USA	For SPC (For NBTS)	Manufacturer registered with premium International.	Product registration has done. No need for a WOR.
6	11/01/2024	MD/19 32/01/ 2024	Therapeutic Plasma Exchange Kits for Fresenius Kabi Comtec Apheresis System	600 (3000 NOS)	LP/DHS/ SUS/WW /2/01NB/ 2023, date: 21/12/20 22	LKR 372,000 ,000.00	Premium International (Pvt) Ltd	Fresenius Kabi AG - Germany	SPC Tender (For NBTS)	ACD not available in the FSC. Not applied for variation.	Recommended only for this consignment.


Prepared By : Mrs. N.B. Ayesha Udayangani

 19/01/2024

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 19/01/2024

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