

Waiver of Registration Committee - Device 23/03/2024

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	22/02/2024	MD/1985/02/2024	Abbott Determine HIV Early Detect 100 Test Kit	19EA / 101E A	135041021, date: 22/12/2023	USD 11,451.84	International Organization for Migration (IOM) (Ministry of Health)	Abbott Diagnostics Medical Co.Ltd - Ireland.	For IOM. (Not a donation)	Submitted to WOR Committee held on 13/01/2024 and Decision was Advised to discuss with NMRA.	Recommended only for this consignment. (Future supplies to be purchased from a registered source in Sri Lanka.)
			Bioline Filariasis Strips 30 Test Kit	200 EA	135040531, date: 11/12/2023	USD 13,189.18		Abbott Diagnostics Medical Co.Ltd - Ireland.	For IOM. (Not a donation)		
			Malaria AG PLDH HRP Combo	(25T/ Pack) 640 Packs	SPI/227/23-24	\$7,200.00		Premier Medical Corporation (Pvt) Ltd - India	For IOM. (Not a donation)		
2	14/03/2024	MD/2013/03/2024	Dynex DS2 Automated ELISA Instrument / QFT-Plus tubes / QFT-Plus 2 Plate Kit / ELISA / Dynex Blue Sample Tips / Dynex White Reagents Tips / Dynex Deep Well Dilution strip / Dynex Control Vials / QuantIFERON Control Panel	As per the invoice	96869884, date: 13/02/2024 / 96870432, date: 14/02/2024	USD 30500.00 + USD 15673.09	International Organization for Migration (IOM)	Qiagen GmbH - Germany	For IOM (Not a donation)		Recommended only for this consignment.

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

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3	20/02/2024	MD/1990/02/2024	Fetal Bovine Serum / L-Glutamine Solution Bioextra	1 + 1	8206473 919, date: 12/01/2024	EUR 145.00 + EUR 38.00	Neochem Lifesciences (Pvt) Ltd	Sigma Aldrich - Germany	For University of Colombo	Request from University of Colombo and University of Peradeniya available.	Pending decision. Need to get ethical clearance or research approval from relevant institution.
4	21/02/2024	MD/1991/02/2024	Human IL-4 (Interleukin) ELISA Kit	1	ED20240 202LKA, date: 02/02/2024	\$278.00	Avon Pharmo Chem (Pvt) Ltd	Wuhan Elabsciences Biotechnology Co.ltd - China	For University of Colombo	For an undergraduate research project of department of Zoology, University of Colombo. ERC approval and request from the University available.	Pending Decision. Advised to submit an ethical clearance.
5	01/03/2024	MD/1997/03/2024	RealStar Enterovirus RT-PCR Kit 1.0, RealStar Adenovirus PCR Kit 1.0, RealStar HHV6 PCR Kit 1.0, RealStar Influenza Screen & Type RT-PCR Kit 4.0, RealStar CMV PCR Kit 1.0, RealStar BKV PCR Kit 1.0, RealStar HCV RT-PCR Kit 2.0	2+2+2 +1+2+ 1+1+1	A24*007 63, date: 22/02/2024	EUR 5710.00	Avon Pharmo Chem (Pvt) Ltd	Altona Diagnostics GMBH - Germany	For Apeksha Hospital and University of Kelaniya	Request from University of Kelaniya and Apeksha Hospital available.	Not recommended and advised to register the product.

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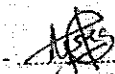
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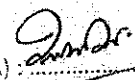
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6	12/03/2024	MD/2009/03/2024	Recombinant Human IL-12 p70 protein (Active), Alpha-MSH (Alpha-Melanocyte-stimulating hormone), Endogenous Melanocortin receptor agonist	1 + 2	405746, date: 26/02/2024	\$ 255.00 + 410.00	Avon Pharmo Chem (Pvt) Ltd	Abcam Singapore Pte Ltd - Singapore	For Kelaniya University and Open University of Sri Lanka	Request for research use from Rajarata University and Open University of Sri Lanka.	Pending Decision. Advised to submit an Ethical Review Committee Approval.
7	15/03/2024	MD/2016/03/2024	Recombinant human interferon alpha 1 protein (Active)	1	405746, date: 07/03/2024	\$340.00	Avon Pharmo Chem (Pvt) Ltd	Abcam Singapore Pte Ltd - Singapore	For Faculty of Technology - University of Rajarata (Research Purpose)	Request for research use from Rajarata University.	Pending Decision. Advised to clarify the usage of this product on the said research or submit the research proposal.
8	15/03/2024	MD/2017/03/2024	ERY Elisa Kit / AMO Elisa Kit / OTC Elisa kit / CAP Elisa Kit	2 + 1 + 1 + 1	ED20240 130LKA, date: 02/02/2024	\$797.50	Avon Pharmo Chem (Pvt) Ltd	Wuhan Elabscience Biotechnology Co.Ltd - China	For National Aquatic Resources Research & Development Agency	Request from NARA for research purpose.	Pending Decision. Advised to submit an Ethical Review Committee Approval.
9	15/03/2024	MD/2018/03/2024	cAMP (Cyclic adenosine monophosphate) Elisa Kit / RPMI-1640 / Recombinant Human Trail Protein (His Tag) (Active)	1+20+2	ED20240 311LKA, date: 11/03/2024	\$844.80	Avon Pharmo Chem (Pvt) Ltd	Wuhan Elabscience Biotechnology Co.Ltd - China	For Faculty of Technology - University of Rajarata (Research Purpose)	Request for research use from Rajarata University.	Pending Decision. Please submit the research proposal and the utilization of the product in this research to which ethical clearance is given.


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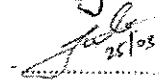
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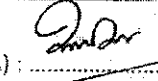
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10	04/03/2024	MD/2001/03/2024	Transport Stretcher (Brand: Linet, Model: Sprint 100)	1	7080003563, date: 30/01/2024	EUR 3732.60	Shield Medical (Pvt) Ltd	Linet - Czech Republic	For Colombo North Centre for Liver Diseases (CNCLD), Faculty of Medicine, University of Kelaniya	Request from Colombo North Center for Liver diseases (CNCLD) is available.	Recommended only for this consignment.
11	31/01/2024	MD/1954/01/2024	Glass Fiber Post/Straight type (Fiber Post)	908	ZG2024-D0036, date: 23/01/2024	\$1,946.80	Abc Pharma Services (Pvt) Ltd	Zogear Medical Co.Ltd - China	For HSEP - AIB	Recommended by College of Dentistry and Stomatology.	Recommended only for this consignment. Advised to submit dossier for registration.
12	15/11/2023	MD/1834/11/2023	Adhesive Dual Cure Compositive (Brand : MultiCore Flow Refill)	528 + 528	01/IVO/ABC/3/2023-24, date: 24/10/2023, 02/IVO/ABC/3/2023-24, date: 24/10/2023	USD 55,440.00 + 55,440.00	ABC Phama Services Pvt) Ltd	Ivoclar Vivadent AG - Schaan, Liechtenstein	For Health System Response Project - AIBB (Health System Enhancement Project)	Recommended by College of Dentistry and Stomatology.	Recommended only for this consignment. Advised to submit dossier for registration
13	12/03/2024	MD/2005/03/2024	Dialysis water production and preparation unit / Reverse Osmosis Unit & Accessories & Spare Parts	As per the invoice	AU24-00351, date: 21.02.24	EUR 23,745.15	Premier Healthcare (Pvt) Ltd	DWA GmbH & Co. KG - Germany	For NHSL	NMRA registered product and expires on 31.03.2024. Local agent applied for renewal in January 2024. Request from NHSL available.	Recommended only for this consignment.

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14	12/03/2024	MD/2007/03/2024	Delta Cut Needle for Delta Cut Gun	1000	35640, date: 04/03/2024	EUR 14,650.00	Ceegeez Associates	PAJUNK GmbH - Germany	For NHSL	NMRA registered product. (DVR-684-RR) Expired and local agent has not applied for renewal due to the unavailability of FSC.	Recommended only for this consignment.
15	14/03/2024	MD/2012/03/2024	Closed Ventilation Suction Catheter with T connector for Tracheostomy Tube	13+13	175300 - 1, 20/03/2024	EUR 6000.80	Sunshine Healthcare Lanka Ltd	Smith Medical ASD Inc - USA	For Sri Lanka Army Hospital	Registered product and expired on february 2024. (DVR- 13985) Applied for renewal. Sri Lanka Army tender award is available.	Recommended only for this consignment. (Registration expired. Dossier is submitted.)
16	22/03/2024	MD/2029/03/2024	Control, Calibrators, Accessories and Spare Parts for Hematology Analyzer	As per the invoice	10051977, date: 14/03/2024, 10051978, date: 14/03/2024, 10045488, date: 29/09/2024, 10048801, date: 22/12/2023	USD 2740.00 + 26053.00 + 758.00 + 57594.32	Hemas Surgicals & Diagnostics (Pvt) Ltd	Nihon Kohden - Japan	For Sri Lanka Air Force	Agency transferred product to Hemas however, they have not applied for registration yet due to a documentation delay from manufacturer.	Not recommended. If reagents for Sri Lanka Air Force and Spare Parts for biomedical engineering. (As per the request letter) needed, two separate application should be submitted. As the Agency transfer process is completed, Advised importer to apply for registration.
17	20/02/2024	MD/1983/02/2024	Miraclefeet Brace Orthotics and Miraclefeet Bars	2432	Sri Lanka 10, date: 02/05/2024	\$23,700.32	Ministry of Health	Miraclefeet - USA	Donation to Lady Ridgway Hospital for Children		Recommended only for this consignment.


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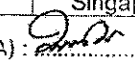
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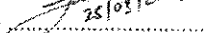
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18	21/02/2024	MD/1986/02/2024	Insulin Delivery Device for Humulin & Humalog Insulin / Insulin Pen Needle 32G x 5/32"(4mm) Sterile Sol-Millennium, 100/Box	365+600	8021584 7-Sri Lanka, Date: 01/02/2024	\$200.00	Ministry of Health	Direct Relief - USA	Donation	Recommended only for this consignment.
19	21/02/2024	MD/1987/02/2024	Dengue Duo NS1 25S	1	PR11699 639, date: 10/01/2024	\$415.34	Ministry of Health	Embassy of the United States of America	Donation	Recommended only for this consignment.
20	28/02/2024	MD/1995/02/2024	ZOLLED Plus Defibrillator / PEDI PADZ II PEDIATRIC MULTI-FUNCTION / CPR-DPADZ ONE PIECE ELECTRODE PAD WITH REAL CPR HELP-CPR-D	7+7+7	PR11677 491, date: 23/05/2023	\$11,359.28	Ministry of Health	Embassy of the United States of America	Donation	Recommended only for this consignment.
21	28/02/2024	MD/1996/02/2024	JE Kits, PT Panels and Dengue Kits	1+1+1	20/2024 (PO:MS-IVD), date: 27/02/2024	INR 21,000.00	Ministry of Health	World Health Organization, South East Asia - India.	Donation	Recommended only for this consignment.
22	04/03/2024	MD/1999/03/2024	Medical Devices/ Equipment's	As per the invoice	HSC/US CAL/240 1, date: 19/02/2024	USD 1738.30	Ministry of Health (Hospital Services Council)	Hospital Services Support Foundation - - USA.	Donation	Recommended only for this consignment.
23	17/01/2024	MD/1942/01/2024	Hospital Equipment's	As per the invoice	0115202 4, date: 14/01/2024	As per the invoice	Mahakaruna Buddhist Society	Mahakaruna Buddhist Society - Singapore	Donation from Mahakaruna Buddhist Society - Singapore	Recommended only for this consignment.

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24	20/02/2024	MD/1988/02/2024	Laboratory Supplies	As per the invoice	001/2024 (PO:2032 18616). Date: 02/01/2024	INR 225,000.00	DDGLS - Ministry of Health	World Health Organization, South-East Asia - India	Donation	Recommended only for this consignment.
25	12/03/2024	MD/2004/03/2024	Patient Monitor / Mobile resuscitation table for neonatal patient / Light, examination, mobile	30+5+5	23/03139, date: 04/10/2023	USD 25,962.40	Ministry of Health	AMEX Healthcare GmbH - Austria	Donation	Recommended only for this consignment.
26	19/03/2024	MD/2019/03/2024	Home Use Ultrasound 1Mhz & 3Mhz Therapy Unit	2	820, date: 12/03/2024	INR 30663.90	Ministry of Health	Next Gen Healthcare - India	Donation from Ms. Janakie Abywardane to NHSL	Recommended only for this consignment.
27	19/03/2024	MD/2020/03/2024	Urinary Catheters (FricOrigo / Coloplast)	15+04	N/A	N/A	Ministry of Health	N/A	Donation to Apeksha Hospital - Maharagama	Recommended only for this consignment.
28	20/03/2024	MD/2021/03/2024	Mortuary Accessories (RD-D 4 boddy refrigerator / RD-A02 Dissecting table / RD-SAW-19 (Anatomy Hand Saw) / RD-904 Dead Body bag)	1+1+1+2	RD20-4002, date: 28/01/2021	USD 8600.00	Ministry of Health	Shenyang Rundfin Trade Co.Ltd - China	Donation from Suwasarana Health Fund to Base Hospital - Horana.	Recommended with condition. Subject to confirmation from hospital.

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29	20/03/2024	MD/2022/03/2024	Hearing Aids	ORD 957/23 - Qty:200, ORD 958/23 - Qty:122	N/A	N/A	Ministry of Health	Lions Club International - Birmingham	Donation		Recommended only for this consignment.
30	20/03/2024	MD/2027/03/2024	Manual Vacuum delivery system Vacca Omnicup	486	0013331, date: 26/01/2024	USD 110,382.36	Ministry of Health	The Medical Export Group BV - The Netherland	Donation		Recommended only for this consignment.
31	22/03/2024	MD/2028/03/2024	Medical Devices/Equipments	As per the invoice	7203261053, date: 03/01/2024	USD 68,575.00	Ministry of Health	Philips Medical System Netherland B.V - The Netherland	Donation to Teaching Hospital - Jaffna		Recommended only for this consignment.
32	22/03/2024	MD/2030/03/2024	Medical Devices/Equipments	As per the invoice	HSC/US CAL/2402, date: 21/03/2024	USD 1687.10	Ministry of Health (Hospital Services Council)	Hospital Services Support Foundation - California	Donation		Recommended with condition. Advised to submit the distribution list.
33	22/02/2024	MD/1993/02/2024	Rubella Virus 1gM	10	CINV00078401, date: 19/02/2024	\$10.00	Medical Research Institute	ATCC - USA	Donation		Recommended only for this consignment.
34	22/02/2024	MD/1994/02/2024	Peet Grady Chamber	1	EXP-SAMPLE -002/SL, date: 14/09/2023	USD 250.00	Medical Research Institute	Godrej Consumer Products Ltd - India	Donation		Recommended only for this consignment.

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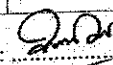
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35	12/03/2024	MD/2006/03/2024	Biological Substances Category B	1	VIPT23, date: 02/15/2024	E 10.00	Medical Research Institute	National Institute for Public Health and the Environment - The Netherland	Donation to MRI	Recommended only for this consignment.
36	15/03/2024	MD/2014/03/2024	Biological Substances Category B Materials	01 Parcel	8586532603, date: 01/03/2024	US \$ 10.00	Medical Research Institute	National Food Institute - Bangkok	Donation	Recommended only for this consignment.
37	15/03/2024	MD/2015/03/2024	Real Time PCR System	03 Packages	155/2023 (PO: 203199176), date: 08/03/2024	INR 137900.00	Medical Research Institute	World Health Organization, South East Asia - India	Donation	Recommended only for this consignment.
38	04/03/2024	MD/2000/03/2024	Capilia TB-Neo 100T/Box (Item No. 106611), Capilia TB-Neo Extraction Buffer 20ml/Bottle (Item No. 106612)	30+30	202401183, date: 18/01/2024	USD 3000+240	National Programme for Tuberculosis Control & Chest Diseases	Tauns Laboratories Inc - Japan	Donation to NPTCCD	Recommended only for this consignment.
39	12/03/2024	MD/2008/03/2024	Gene Xpert MTB/RIF Ultra Kit	500	9001588217, date: 14/02/2024	USD 202200.00	National Programme for Tuberculosis Control & Chest Diseases	Cepheid AB - Sweden	Donation	Recommended only for this consignment.
40	20/03/2024	MD/2024/03/2024	Sterilizer System and Standard Accessories and Spare Parts	As per the invoice	8085415180, date: 06/03/2024	USD 47,688.95	Mediquipment Limited	Getinge AB - Sweden (Legal) /Setinge Sterilization AB - Sweden (Physical)	For Division of Biomedical Engineering Services	Recommended only for this consignment. (For HS-66 Model)

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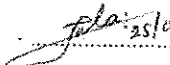
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41	20/03/2024	MD/2025/03/2024	Novatech Steritalc - Talc Powder Sterile 4g bottles	50	N/A	N/A	Instrumendc International (Pvt) Ltd	Novatech SA - France	For the National Hospital for Respiratory Diseases	Local Agent applied for manufacturing site registration. FMSA/MD/2023/524	Recommended only for this consignment. (Small Quantity)
42	20/03/2024	MD/2026/03/2024	Gel filled textured mammary implant	224	date: 26/02/2024	EUR 53153.30	CIC Holdings PLC	Nagor Limited - United Kingdom	For Several Government Hospitals in Sri Lanka		Not recommended and advised to register the product.
43	23/05/2023	MD/1560/05/2023	Wallace Catheters & Oocyte Recovery Set	420	OIPL/23-24/PI/AB/001, date: 27/04/2023	\$29,652.00	A. Baur & Co. (Pvt) Ltd	Cooper Surgical Inc - USA	For Several Private Hospitals in Sri Lanka		Recommended only for this consignment.


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Waiver of Registration Committee - Device 23/03/2024 - S.P.C

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	20/02/2024	MD/1989/02/2024	Mechanical Hemostatic Bone Wax Contain Natural Bees Wax and Vaseline	375 Pack (9000 NOS)	DHS/SW W/41/136 CP/2022, date: 08/07/2022	EUR 16470.00	B. Braun Lanka (Pvt) Ltd	B. Braun Surgical S.A - Spain	SPC Tender	NMRA registered product. (Ref: D/859/RR). Applied WOR due to the manufacturing site change. Local agent not applied for registration.	Recommended only for this consignment subject to submission of site registration documents.
2	21/02/2024	MD/1992/02/2024	Silicone Sheeting, size approximately 25mmx25mm	50 NOS	LP/DHS/S /WW/8/17 6MT/23, date: 11/01/2024	LKR 1140000.00	Shimmer's	EON Meditech Pvt Ltd - India	SPC Tender	SPC Indent available. No other registered sources found.	Recommended only for this consignment. (Due to the low volume of need)
3	11/01/2023		Bacterial and Viral Filter Paediatric / Incentive Spirometer for Paediatric, disposable	18000 + 6000	DHS/ICL/ X/RS/053/ 340AK/22, date: 17/10/2022	US\$ 53,160.00	Medigrow International SS (Pvt) Ltd	Browndove Healthcare (Pvt) Ltd - India	SPC ICI Tender	Submitted to WOR Committee held on 15/07/2023 and Decision was Recommended only for this consignment of Spirometers. Bacterial and Viral Filter Paediatric should be sent to college of Microbiologists. (The samples were sent to the College of Microbiology. They were referred it to the College of Anaesthesiology. College of Aneasthesiology report is attached.)	Not recommended and advised to re-export the product. (Does not confirm to evaluation specification)

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4	01/09/2023	MD/1724/09/2023	Ring pressaries/Pol ythene/size 68mm external diameter/semi rigid/smooth finish/clinically clean	As per the invoice	DSH/SW/ W/05/23, date: 07/02/2023	LKR 91,837,149.00	Sunshine Healthcare Lanka (Pvt) ltd	Cooper Surgical Inc - USA	SPC Tender	Product file has been submitted for registration on 2024 February. (D/5242). Submitted to WOR Committee held on 05/09/2023 and Decision was Recommended only for this consignment Subject to submission of dossier for registration. NMRA issued WOR Letter on 09/11/2023. Sunshine Healthcare Lanka Limited has cleared 1st lot of the shipment. Sunshine Healthcare Lanka Limited has requested for WOR extension to Clearance of 2nd lot.	Not recommended. Advised to expedite the registration.
5	11/07/2023	MD/1638/07/2023	Hearing aid and standard accessories	17500	LP/DHS/ M/S/WW/ 12/874MT /21, date: 02/05/2023	LKR 790,125,000.00	D.S. Jayasinghe Optician (Pvt) Ltd	Sivantos GmbH - Germany	SPC Tender	Submitted to WOR Committee held on 12/08/2023 and Decision was Recommended only for this consignment. Advised to register the new site. NMRA issued WOR Letter on 15/08/2023. DS Jayasinghe Opticians has cleared 1st lot of the shipment. DS Jayasinghe Optician has requested for WOR extension to Clearance of 2nd lot.	Recommended only for this consignment. (Awaiting site registration. Product from European country. No previous complaints.)

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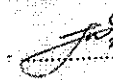
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6	15/02/2024	MD/1974/02/2024	Instrument Set for Proximal Femur Anti Rotation Nailing System (Brand: Miraclus)	30	LP/DHS/RSS/RQ/81/29BS/23, date: 05/10/2023	LKR 14220000.00	Avenierr Pharma (Pvt) Ltd	Miraclus Orthotech Pvt Ltd - India	SPC Tender	Variation documents has been submitted on 12/03/2024. (ref: D/3295). Submitted to WOR Committee held on 17/02/2024 and Decision was Not recommended and register the product.	Recommended with conditions. <ul style="list-style-type: none"> • Subject to get the recommendation from the college of Orthopedic. • Need to forward the dossier for evaluation.
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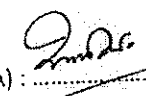
Prepared By : Mrs. N.B. Ayesha Udayangani

 25/03/2024

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

 25/03/2024

CEO (NMRA) :



Dr. Saveen Semage
 MBBS, MSc, MD
 Chief Executive Officer
 National Medicines Regulatory Authority
 No. 136, Narin