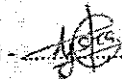


Waiver of Registration Committee - Device 17/02/2024

No	Date of Submission	NMRA Ref: Number	Item	Qty	Invoice / Tender Number	Invoice Value	Applicant	Manufacturer / Supplier	Reason for WOR	Remarks	WOR Committee Recommendation
Private Institution to Government institution											
1	02/08/2024	MD/1964/02/2024	Spare Parts of Next Generation Sequencing System (Brand: Illumina) (Model: Nextseq 550 system)	1	1400325388, date: 24/11/2023	USD 4040.05	Hayleys Lifesciences (Pvt) Ltd	Illumina - USA	For Sri Lanka Institute of Biotechnology (Research Use Only)	<ul style="list-style-type: none"> Request to clear spare parts imported for "Nextseq 550" sequencing system at SLIBTEC. (Research use only system) 	Recommended only for this consignment.
2	05/02/2024	MD/1960/02/2024	Sterilizer System and standard Accessories and Spare Parts	As per the invoice	8085414983, date: 23/01/2024	USD 2511.57	Mediquipment Limited	Getinge AB - Sweden	For Army Headquarters	<ul style="list-style-type: none"> Request to import accessories and spare parts for already registered sterilizer. (Discontinued model HS-66) 	Recommended only for this consignment.
3	17/01/2024	MD/1951/01/2024	Nidek - A Scan & OCT Machine (Brand : Nidek)	As per the invoice	SN202311-0429, date: 24/11/2023	JPY 956.770	Vision 2020 Techno	Nidek Co.Ltd - Japan	For National Eye Hospital	<ul style="list-style-type: none"> Registered products and agency transfer is ongoing to Vision 2020 Techno from Hayleys. NOL from Hayleys available. Request from National Eye Hospital available. 	Recommended only for this consignment.

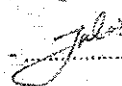
Prepared By : Mrs. N.B. Ayesha Udayangani

 18/02/2024

CEO (NMRA)



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

 19/02/2024

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4	19/01/2024	MD/1948/01/2024	Hypo-Hyperthermia Therapy Device for neonates	As per the invoice	SO23007624, date: 06/12/2023	EUR 4,529.90	Premium International (Pvt) Ltd	TecCom GmbH - Germany	For Division of Biomedical Engineering Services	<ul style="list-style-type: none"> Previously registered product and expired. (Ref: No: D-2514, exp: date: 23.06.2022). Product is discontinued by manufacturer therefore, renewal not done. Request to supply accessories for an installed machine. 	Recommended only for this consignment.
5	22/12/2024	MD/1901/12/2023	Nebulizer	20	INV-2023/24-1376, date: 14/12/2023	Euro 6,800.00	Premium International (Pvt) Ltd	Aerogen Limited - Ireland	For New Maternity Hospital - Karappitiya	<ul style="list-style-type: none"> Previously registered product. Not renewed the registration. (DVR-14782, Exp: 27.03.2023). 	Not Recommended and advised to register the product.

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6	17/01/2024	MD/1944/01/2024	Indirect and Direct antiglobulin Test/ ABO/RH blood grouping combined with reverse grouping/Determination of the ABO/RH blood groups with direct antiglobulin test for Newborns - DiaClon ABO/Rh for Newborn Grouping.	As per the invoice	BRI/CDG /06/23, date: 03/11/2023 ; BRI/CDG /02/23, date: 23/11/2023	2257.00 + 216.00	Emar Pharma (Pvt) Ltd	Legal M/F : Bio-Rad - France, Physical M/F : M/s. DiaMed GmbH - Switzerland	For Army Headquarters	<ul style="list-style-type: none"> For Sri Lanka Army tender award. 	Not Recommended and Advised to Register the Product.
7	16/02/2024	MD/1980/02/2024	Automatic Urine Chemistry Analyzer with reagent, consumables, standard accessories, spare parts	1+1	2023CE2 331, date: 23/11/2023	US \$ 1563.00	Surgicare (Pvt) Ltd	Dirui Industrial Co.Ltd - China	Office of the Provincial Director of Health Services - Western Province	<ul style="list-style-type: none"> Already registered product with NMRA. (ref: D/3082) Request to import several spare parts as the local agent still has not approved the full spare parts list. Request from TH-Karapitiya and provincial director of Health Services - Western Province available. 	No recommended and advised to apply for a variation.


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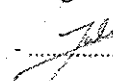
CEO (NMRA) :

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8	16/02/2024	MD/1982/02/2024	Automated Slide Stainer with drying station	2	4034/0124B, date: 23/01/2024	EUR 198.64	Biomedica (Pvt) Ltd	Especialidade s Medicas MYR - Spain	For Ashraff Memorial Hospital - Kalmunai	• Request form Ashraff Memorial Hospital is available.	Not recommended and advised to apply for product registration.
For Research Purpose											
9	31/01/2024	MD/1955/01/2024	Vacutainer Glass Sodium Heparin Tube, Vacutainer Plastic K2 EDTA Tube, Vacutainer Plastic PAXgene Blood RNA Tube, Nanopore Sequencing Reagents (Brand : BD)	As per the invoice	1027943-3, date: 18/01/2024	USD 5,731.70	Prof. A.D. De Silva, Head of Biomedical Laboratory - 2, Department of Para-Clinical Sciences, Faculty of Medicine, General Sir John Kotelawala Defence University	BD - United Status, Oxford Nanopore Technologies - UK	For Research Purpose	• For a research purpose. ERC approval available.	Recommended only for this consignment.
10	31/01/2024	MD/1956/01/2024	Handheld Retinal Imaging Device (FOP-NM 10 by Remidio)	2	PINV-I-2023/0009, date: 11/07/2023	\$10,050.00	Institute of Health Policy	Remidio Innovation Solution (Pvt) Ltd - India	For Research Purpose	• For a research purpose. ERC approval available.	Recommended only for this consignment.
Others											


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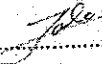
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11	07/12/2023	MD/1882/12/2023	Mini MS Unit (New Series), Advanced 5 in 1 Combi Therapy Unit, MS-10 (4 socket), 4 Channel TENS + TENS, TENS+US, Set of Mini MS Accessories	3+1+1 +1+1+ 3	TNTIN24 5, date: 28/11/20 23	INR 37280	R.M.T. Sampath Kumara	The Necessities Town - India	For Custom detaim	• Manufacturer not registered.	Not recommended and advised to register the product.
Donation to MOH											
12	11/01/2024	MD/1931/01/2024	Mobile Maternity Unit, Medical Equipment (a,b,c,d,e,f,g), Sea Freight	3+3+3	2023122 1_SRI01, date: 21/12/20 23	USD 315,000 .00	Ministry of Health	turmaks Insaat Tur.ilet - Ankar	Donation	• Donation	Recommended only for this consignment. Advised to submit the distribution list.
13	19/01/2024	MD/1940/01/2024	SIARETRON4000, Automatic Ventilator for adult, Mobilite LED Phototherapy Unit AC powered including accessories	2 + 2	23/04025 date:10/0 1/2024	USD 46,393. 84	Ministry of Health	AMEX Healthcare GmbH - Austria	Donation from United Nations Children's Fund - Denmark	• Donation from United Nations Children's Fund to Government of Sri Lanka.	Recommended only for this consignment.
14	22/01/2024	MD/1941/01/2024	Patient Monitor iM60, with 10.4" color TFT LCD LCD Monitor, 3/5-lead ECG, HR, RESP, SpO2, NIBP, PR, 2-TEMP	50	0013310, date: 19/01/20 24	USD 80,770. 00	Ministry of Health	The Medical Export Group BV - The Netherland	Donation from United Nations Children's Fund - Denmark	• Donation from United Nations Children's Fund to Government of Sri Lanka.	Recommended only for this consignment. Advised to submit the distribution list.

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 19/02/2024


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15	17/01/2024	MD/1942/01/2024	Hospital Equipment's	As per the invoice	01152024, date: 14/01/2024	As per the invoice	Mahakaruna Buddhist Society	Mahakaruna Buddhist Society - Singapore	Donation from Mahakaruna Buddhist Society - Singapore	• Donation	Pending Decision. Advised to submit the previous distribution list.
16	17/01/2024	MD/1943/01/2024	SS OT Table , Digital Vision Chart (22 inch)) , OT Chair wireless model	3+1+2	EX2324 QU-1258, date: 26/12/2023	USD 5,138.00	Ministry of Health	aurolab - India	Donation from Kanagaambik Pawn Brokers	• Donation to Teaching Hospital - Jaffna.	Not recommended and advised to register the product. Advised to purchase from registered sources.
17	26/01/2024	MD/1949/01/2024	Laboratory Supplies (Room Temperature)	As per the invoice	158/2023 (PO: 203218592), date: 04/12/2024	INR 1,653,636.00	Ministry of Health	World Health Organization, South East Asia - India	Donation	• Donation from WHO.	Recommended only for this consignment.
18	26/01/2024	MD/1950/01/2024	Used Oticon Hearing Aids / Heine Mini 3000 Otoscope including 110 Ear Tips	354 + 1	RM436877294DE -Sri Lanka , date: 15/01/2024	EUR 117.00 + EUR 102.35	Ministry of Health	Lions Foundation Germany - Germany	Donation	• Donation from Lions Foundation, Germany to Ceylon School for the deaf and blind.	Recommended only for this consignment.
19	02/02/2024	MD/1957/02/2024	Medical Devices/Equipments	As per the invoice	Seal No: C9504307, date: 20/01/2024	42,537.00	Dhahamsewana Singitho Foundation. (Ministry of Health)	Care Giver Support Network - Japan	Donation	• Donation	Recommended only for this consignment.

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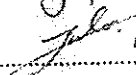
20	16/01/2024	MD/1963/02/2024	MGE-ED2 Hospital Bed Set, MGE-M31 Hospital Bed Set, MGE-BN3B NewBorn incubator, MGE-BW3B NewBorn Warmer, Disposable 32G Pen Nedges in Blister Pack Manufactured 2023/12 Expiration 2028/11 ISO-13485 (Sterile)	17+13 +1+1+ 160,000	1701744 099, date: 12/05/2023	\$1,345.00	Ministry of Health	Medical Help International - USA	Donation from Medical Help International	<ul style="list-style-type: none"> Request from NHSL and Base Hospital - Dehiattakandiya are available. 	Recommended only for this consignment.
21	09/02/2024	MD/1969/02/2024	Measles Rubella Kits (Perishable)	14	012/2024 (PO: 2032273 53 (MS-IVD)), date: 01/02/2024	INR 210,000.00	Ministry of Health	World Health Organization, South-East Asia - India	Donation to MRI	<ul style="list-style-type: none"> Donation from WHO. 	Recommended Only for this consignment.
22	09/02/2024	MD/1972/02/2024	Surguad Needle / 1ml Syringe / Semi Blunt Sterican Cannula	4800+ 5000 + 10000	INV/2024 /00026, date: 24/01/2024	\$198.00	Ministry of Health	World Federation of Hemophilia - Canada	Donation to NHSL	<ul style="list-style-type: none"> Humanitarian aid donation from World Federation of Hemophilia. 	Recommended only for this consignment.
23	16/02/2024	MD/1978/02/2024	Medical Devices/Equipmen t's	100	0012755, date: 26/10/2023	USD 14274.00	Ministry of Health	The Medical Export Group BV - The Netherland	Donation from United Nations Population Fund - Denmark	<ul style="list-style-type: none"> Donation 	Recommended only for this consignment. Advised to submit the distribution list.

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 19/02/2024

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 19/02/2024

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24	16/02/2024	MD/1979/02/2024	Disposable temperature data logger Libero CB, PDF logger with internal NTC probe.	2	0012754, date: 27/10/2023	USD 64,787.00	Ministry of Health	The Medical Export Group BV - The Netherland	Donation from United Nations Population Fund - Denmark	• Donation	Recommended only for this consignment.
Donation to Other Government Institution											
25	02/02/2024	MD/1959/02/2024	Blood Pressure Monitor	92 Units	APEC 1866, date: 06/11/2023	GBP 3285.00	Sri Lanka College of Endocrinologists	Microlife AG - Switzerland	Donation to Sri Lanka College of Endocrinologists	• For a collaborative programme of MOH, Endocrinology College and World Diabetes Foundation. (Blood Pressure Monitors for Community Screening).	Pending Decision. Advised to submit the Ethical Committee Approval.
26	02/08/2024	MD/1965/02/2024	Laboratory Reagents	2	CINV000 77919, date: 02/01/2024	USD \$ 2.00	Medical Research Institute	ATCC - USA	Donation to MRI	• Donation from Center for diseases Control and Prevention - USA to the MRI.	Recommended only for this consignment.
27	02/08/2024	MD/1966/02/2024	Measles IgM ELISA Test Kits	13	CINV000 77917, date: 02/01/2024	USD \$ 8.00	Medical Research Institute	ATCC - USA	Donation to MRI	• Donation from Center for diseases Control and Prevention - USA to the MRI.	Recommended only for this consignment.

Prepared By : Mrs. N.B. Ayesha Udayangani

[Signature] 19/02/2024

CEO (NMRA) : *[Signature]*

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28	05/02/2024	MD/1961/02/2024	L-Asparagine Monohydrate	10	2024-1240005, date: 10/01/2024	US \$ 216.00	National Programme for Tuberculosis Control & Chest Diseases	Global Drug Facility - Switzerland	Donation	• Humanitarian aid to the National Programme for Tuberculosis Control & Chest Diseases	Recommended only for this consignment.
29	05/02/2024	MD/1962/02/2024	LPA Consumables	As per the invoice	90751642, date:	EUR 2302.00	National Programme for Tuberculosis Control & Chest Diseases	Hain Lifesciences GmbH - Nehren	Donation	• Humanitarian aid to the National Programme for Tuberculosis Control & Chest Diseases	Recommended only for this consignment.
30	09/02/2024	MD/1968/02/2024	First Response Malaria AG PLDH/HRP2 Combo 25T Kit	16000	SPI/227/23-24, date: 01/02/2024	\$7,200.00	International Organization for Migration (IOM)	Premier Medical Corporation (Pvt) Ltd - India	For IOM's health assessment facility	• Previously WOR given NMRA/EC/WOR/DVR/209/2023 on June 2023.	Not recommended and advised to register the product.
31	15/02/2024	MD/1975/02/2024	Measles IgM ELISA test Kits and Measles Real time PCR test Kits	12	CINV00078022, date: 06/02/2024	\$4.00	Medical Research Institute	ATCC - USA	Donation to MRI	• Donation to MRI.	Recommended only for this consignment.

Prepared By : Mrs. N.B. Ayesha Udayangani

[Signature] 19/02/2024

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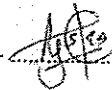
Checked By : Ms. H.M.O.I. Priyashantha

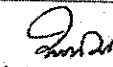
[Signature] 19/02/2024

Dr. Saroon Samage
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
32	15/02/2024	MD/1977/02/2024	Neonatal TSH, Neonatal G6pD, neonatal 17-OH-Progesterone, LTS Rainin 250ul tips	60+15+15+30	CA/1084 24D/013 4/001, date: 28/11/2023	47,652.69 EUR	Medical Supplies Division	Labsystems Diagnostics Oy - Finland	For NMU - Ruhuna	• Reagents for NMU - Ruhuna.	Recommended only for this consignment.
Donation to MOH - Extension											
33	16/01/2024	MD/1752/09/2023	Medical Devices/Equipments	As per the invoice	KW2023 0912, date: 12/09/2023	US 41,500.00	Ministry of Health	KitWell Co.Ltd - Taiwan	Donation from Cao Zhong Zhi Foundation	• WOR extension request for a donation.	Recommended only for this consignment.
34	17/01/2024	MD/1727/09/2023	Defibrillator and Patient Monitors	20 + 100	2032276 96, date: 25/08/2023	USD 209,359.20	Ministry of Health	World Health Organization and Logistics - Malaysia	Donation from WHO	• WOR extension request for a donation.	Recommended only for this consignment. Advised to submit the distribution list and to ensure all audio/visual instructions given by the defibrillator and instruction manual are in English.
35	13/02/2024	MD/1773/10/2023	Medical Devices/Equipments	27	2032547 92, date: 25/09/2023	INR 406922 6.00	Ministry of Health	World Health Organization, Global Procurement and Logistics - Malaysia	Donation (Extention)	• WOR extension request for a donation.	Recommended only for this consignment.

Prepared By : Mrs. N.B. Ayesha Udayangani -

 19/02/2024


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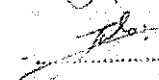
 19/02/2024

Waiver of Registration Committee - Device 17/02/2024 - 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	12/01/2024	MD/1934/01/2024	ACD-A Anticoagulant Solution 500ml	2100	LP/DHS/SUS/WW/1/07/NB/2023, date: 13/12/2023	LKR 136,500,000.00	Emar Pharma (Pvt) Ltd	Infomed Fluids - Romania	SPC Tender (For NBTS)	<ul style="list-style-type: none"> Previously registered product and site changed. Applied for site registration FMSA/MD/2022/318. NBTS/MSD/SPC/ Stock review meeting minute available. 	Recommended only for this consignment.
2	12/01/2024	MD/1935/01/2024	ACD-A Anticoagulant Solution 500ml (Code 10245)	800 KIT	LP/DHS/RSS/RQ/233/639N B/2021, date: 01/03/2023	LKR 48,000,000.00	Emar Pharma (Pvt) Ltd	Infomed Fluids - Romania	SPC Tender (For NBTS)	<ul style="list-style-type: none"> Previously registered product and manufacturing site changed. Applied for site registration FMSA/MD/2022/318. SPC indent available. 	Recommended only for this consignment.
3	17/01/2024	MD/1945/01/2024	DNA Whole Blood Kit	2160 EXT	LP/DHS/RJ/EP/4/25NK/2023, date: 22/12/2023	LKR 3867421.68	Emar Pharma (Pvt) Ltd	RBC Biosciences Corp - Taiwan	SPC Tender (For NBTS)	<ul style="list-style-type: none"> SPC tender. (For NBTS supply). Sample Import License applied for "MagCore" Automated NA extractor. (Ref: SIL/MD/2023/090) 	Recommended only for this consignment.

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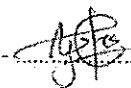
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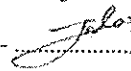
Dr. Saveen Samago
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4	17/01/2024	MD/1946/01/2024	HLA Reagents and Consumables	As per the invoice	LP/DHS/RL/EP/3/24WAC/2023, date: 22/12/2023	LKR 9,461,703.42	Emar Pharma (Pvt) Ltd	One Lambda Inc - USA	SPC Tender (For NBTS)	<ul style="list-style-type: none"> Previously issued WOR on July 2023 for NBTS supply. 	Recommended only for this consignment.
5	19/01/2024	MD/1947/01/2024	Microtome Blades	As per the invoice	LP/DHS/RL/31/18SM/23, date: 26/09/2023	LKR 30,975,000.00	Times HealthCare International (Pvt) Ltd	Kai Industries Co. Ltd - Japan	SPC Tender (For Patient Care in National Hospitals)	<ul style="list-style-type: none"> Manufacturer is registered with Vision 2020 Techno. Registered Sources (04). (Tanyo Medical, Premium International, Analytical Instruments, P&T Trading.) 	Not recommended. Advised to purchase from registered sources.
6	05/12/2023	MD/1884/12/2023	Single use hypodermic syringe 5ml	9000 packs	SPC/ICL/NS/097/23, date: 28/08/2023	USD 43,020.00	Citihealth Imports (Pvt) Ltd	Hindustan Syringe & Medical devices (Pvt) Ltd - India	SPC ICL Request	<ul style="list-style-type: none"> Registered product expired on 2021 and not renewed. Previously issued WOR available via SPC/ICL pathway. 	Not recommended. Advised to renew the registration.
7	29/12/2023	MD/1911/01/2024	Auto Disable Syringe 1ml (Brand: KOJAK SELINGE)	3500 NOS (350,000 pack)	DHS/RSS/RQ/20/35DR/2023, date: 26/10/2023	LKR 18,655,000.00 (USD 8,655.00)	Citihealth Imports (Pvt) Ltd	Hindustan Syringe & Medical Devices (Pvt) Ltd - India	SPC Tender	<ul style="list-style-type: none"> Previously registered product and expired in 2022. Not renewed. Only one other registered source available for auto disable syringes. 	Not recommended. Advised to renew the registration.

Prepared By : Mrs. N.B. Ayesha Udayangani

 19/02/2024

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

 19/02/2024

CEO (NMRA) : 

8	11/12/2023	MD/1895/12/2023	Vessel Cannulas	80	DHS/RQ/36MT/21, date: 28/11/2023	LKR 284,000.00	Meditek Devices (Pvt) Ltd	Andocor n.v - Belgium	SPC Tender	<ul style="list-style-type: none"> Local Agent hasn't applied for product registration. Request for SPC Tender. 	Not recommended and advised to register the product.
9	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	<ul style="list-style-type: none"> Local agent has not applied for the product registration. 	Not recommended and advised to register the product.
10	05/12/2023	MD/1072/09/2022	Cerclage Wire, Soft, tissue compatibles	As per the invoice	DHS/SUS/WWW/72/543BS/21, date: 25/03/2022	LKR 764,144.50	Medisurge International (Pvt) Ltd	M/s Sigma Surgical (Pvt) Ltd - India	SPC ICL WOR Extension	<ul style="list-style-type: none"> Request for WOR Extension. Samples sent to College (Sri Lanka Orthopaedics Association) and Recommended. 	Recommended only for this consignment. Advised to get the registration from next consignment.

Prepared By : Mrs. N.B. Ayesha Udayangani

[Signature] 19/02/2024

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

[Signature] 19.02.2024

CEO (NMRA) :

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