



## LIST OF EXEMPTED DEVICES AND SUPPLIERS

Application / Letter Reference Number	Product Name	Model Name /Number/ Brand Name	Applicant Details	Manufacturer Details	Date of Approval	Quantity Approved
MRS/EX/MD/2 3/ VOL 01/0060	BD Multitest with Trucount Tubes 342447	BD Multitest with Trucount Tubes (Becton Dickinson)	MedPoint Diagnostics Pty Ltd	Becton Dickinson and Company (BD)	01/02/2024	30 -
MRS/EX/MD/2 3/ VOL 01/0060	BD CS&T Beads	BD CS&T Beads (Becton Dickinson)	MedPoint Diagnostics Pty Ltd	Becton Dickinson and Company (BD)	01/02/2024	130 -
MRS/EX/MD/2 3/ VOL 01/0060	BD Facscount Reagent KIT 25 TESTS	BD Facscount Reagent KIT (Becton Dickinson)	MedPoint Diagnostics Pty Ltd	Becton Dickinson and Company (BD)	01/02/2024	100 -
MRS/EX/MD/2 4/ VOL 01/0019	One Step HCG Pregnancy Test (Colloidal Gold)	One Step HCG Pregnancy Test (Colloidal Gold)	Dynamic Vitality(Pty)Ltd	Nantong Diagnos Biotechnology Co.Ltd	06/02/2024	100 -
MRS/EX/MD/2 4/ VOL 01/0038	Medical oxygen Generator	Sumer Medical Oxygen Generator	Mockair Technologies (Pty) Ltd	Sumer uluslararası sanayi ve ticaret A.s	09/02/2024	6 -
MRS/EX/MD/2 4/ VOL 01/0029	HIV TEST KIT	UNIGOLD HIV TEST KIT	Eagle Systems (PTY) LTD	Trinity Biotech	09/02/2024	5000 -



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MRS/EX/MD/2 4/ VOL 01/0032	TRINSCREEN	HIV TEST KIT	Eagle Systems (PTY) LTd	Trinity Biotech	13/02/2024	2000 -
MRS/EX/MD/2 4/ VOL 01/0027	HEMOCHRON SIGNATURE ELITE	HEMOCHRON SIGNATURE ELITE	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Accriva Diagnostics Inc	14/02/2024	10 -
MRS/EX/MD/2 4/ VOL 01/0003	SURGICAL MASK	WINNER	SANFU TRADING	Winner Medical Co. Ltd	27/02/2024 00:00	20000 BOXES -
MRS/EX/MD/2 4/ VOL 01/0022	ABO Blood Grouping Cells	BIOTEST	Orthosurge Botswana Proprietary Limited	Bio-Rad Medical Diagnostics GmbH	27/02/2024	10000 -
MRS/EX/MD/2 4/ VOL 01/0069	Aptima specimen Transfer Kit ( Including Aptima Transfer Solution	Aptima Specimen Transfer kit ( including Aptima Transfer Solution	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Hologic Inc ,	29/02/2024	1500 -
MRS/EX/MD/2 4/ VOL 01/0068	Aptima Auto Detect Kit	Aptima Auto Detect kit	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Hologic Inc ,	29/02/2024	1500 -



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MRS/EX/MD/2 4/ VOL 01/0075	POWDER FREE NITRILE LATEX GLOVES	PROTECTS	FARRI INDUSTRIES PTY LTD	Semperit Investments Asia Pte. Ltd	29/02/2024	1580 CARTONS -
MRS/EX/MD/2 4/ VOL 01/0084	FARMASOL	FARMACART B Cartridge	TATI RIVER CLINIC/ RIVERSIDE HOSPITAL PHARMACY	FARMASOL TIBBI URUNLER SAN.VE TICAS	06/03/2024	1000 -
MRS/EX/MD/2 4/ VOL 01/0043	Collatamp G	Collatamp G	Fine Pharmaceuticals Ltd	SERB SA	08/03/2024	200 Each -
MRS/EX/MD/2 4/ VOL 01/0046	Skore Nothing Strawberry	Skore Nothing Strawberry condoms	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	14/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -



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MRS/EX/MD/2 4/ VOL 01/0048	Skore Skin Thin	Skore Skin Thin condoms	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	18/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
MRS/EX/MD/2 4/ VOL 01/0050	Male condoms	Skore Time Less	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	26/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
MRS/EX/MD/2 4/ VOL 01/0091	Smart Dialysis Chair	MoneMedical	Jalo Enterprise (PTY) Ltd	MoneMedical	26/03/2024	1 -
MRS/EX/MD/2 4/ VOL 01/0089	Hemodialysis Machine	SWS 6000	Jalo Enterprise (PTY) Ltd	SWS Hemodialysis Care Co., Ltd	26/03/2024	1 -



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MRS/EX/MD/2 4/ VOL 01/0045	Male condoms	Skore Nothing Chocolate	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	26/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
MRS/EX/MD/2 4/ VOL 01/0047	Male Condoms	Skore Nothing Climax Delay	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	26/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
MRS/EX/MD/2 4/ VOL 01/0049	Male Condoms	Skore Zig Zag	Population Services International, South Africa	TTK Healthcare Limited – Protective Devices Division	26/03/2024	31104 condoms (10368 x packs of 3 condoms per pack) -



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TRCMRS/EX/MD/24/ VOL 01/0140	Activated Clotting Time Low Range	Hemochron ACT-LR	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Accriva Diagnostics, Inc	15/04/2024	200 -
TRCMRS/EX/MD/24/ VOL 01/0125	DynaDress Surgical Incise Film	DynaDress	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	15/04/2024	1000 -
TRCMRS/EX/MD/24/ VOL 01/0139	Syphilis Ultra Rapid Test Strip (Whole Blood/Serum/Plasma)	ABON	Orthosurge Botswana Proprietary Limited	Abon Biopharm (Hangzhou) Co. Ltd	22/04/2024	5000 -
TRCMRS/EX/MD/24/ VOL 01/0136	STERILE SUTURES	KOLLSUT-USA	BABILI INVESTMENT PTY LTD T/A BABILI MEDICAL	KOLLSUT INTERNATIONAL INC.	24/04/2024	50000 -
TRCMRS/EX/MD/24/ VOL 01/0124	DynaDress Silver Foam Dressing	DynaDress	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	15/04/2024	1000 -



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TRCMRS/EX/MD/24/ VOL 01/0110	Roosin Calcium Alginate Wound Dressings	Roosin	Aesthetic Inclines T/A A.I. Health	Roosin Medical Co.,Ltd	15/04/2024	500 Boxes -
TRCMRS/EX/MD/24/ VOL 01/0121	DynaDress Transparent Chlorhexidine Gluconate (CHG) IV	DynaDress	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	16/04/2024	500 -
TRCMRS/EX/MD/24/ VOL 01/0120	DynaDress Transparent Adhesive Dressings	DynaDress	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	16/04/2024	1000 -
TRCMRS/EX/MD/24/ VOL 01/0122	DynaMed Dressing Tray	DynaMed	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	16/04/2024	500 -
TRCMRS/EX/MD/24/ VOL 01/0111	Roosin Silver Calcium Alginate Dressings	Roosin	Aesthetic Inclines T/A A.I. Health	Roosin Medical Co.,Ltd	15/04/2024	500 Boxes -



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TRCMRS/EX/MD/24/ VOL 01/0123	DynaDress Non-Woven Island Dressing	DynaDress	Aesthetic Inclines T/A A.I. Health	Dynamed Pharmaceuticals (Pty) Ltd	10/04/2024	2000 -
TRCMRS/EX/MD/24/ VOL 01/0113	Roosin Hydrocolloid Dressing	Roosin	Aesthetic Inclines T/A A.I. Health	Roosin Medical Co.,Ltd	10/04/2024	500 Boxes -
TRCMRS/EX/MD/24/ VOL 01/0109	MedCu Antimicrobial Copper Dressings	MedCu	Aesthetic Inclines T/A A.I. Health	MedCu Technologies Ltd.	10/04/2024	500 Boxes consisting of 10 sheets each -
TRCMRS/EX/MD/24/ VOL 01/0114	Hydrogel Dressings	Roosin	Aesthetic Inclines T/A A.I. Health	Roosin Medical Co.,Ltd	10/04/2024	500 Boxes -
TRCMRS/EX/MD/24/ VOL 01/0147	Sample cups 3 mL	ILab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	08/05/2024	500 -
TRCMRS/EX/MD/24/ VOL 01/0112	Roosin Burn Gel Dressing	Roosin	Aesthetic Inclines T/A A.I. Health	Roosin Medical Co.,Ltd	11/04/2024	500 Boxes -





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TRCMRS/EX/MD/24/ VOL 01/0145	Reference Electrode Housing	ILab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	20/05/2024	50 -
TRCMRS/EX/MD/24/ VOL 01/0155	Reaction Cuvettes	ILab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	23/05/2024	200 -
TRC/MRS/EX/MD/24/ VOL 01/0162	Urine DoA Beta Controls	QauntilLab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	23/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0164	Urine DoA Zeta Controls	QauntilLab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	24/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0171	Urine DoA Ecstasy Calibrators	QauntilLab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	24/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0163	automatic Insulin pen injection	Gensupen 2	Medic Plus Pharmaceuticals	BIOTON S.A.	24/05/2024	10000 -



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TRCMRS/EX/MD/24/ VOL 01/0128	Urine DoA Ethyl Alcohol Calibrators	Qauntilab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	24/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0166	Urine MultiDoA Calibrator	Qauntilab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	24/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0172	Acquire™ S Endoscopic Ultrasound Fine Needle Biopsy (FNB) Device	Acquire	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -
MRS/EX/MD/24/ VOL 01/0055	CrossBoss™ Catheter	CrossBoss™ Catheter	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -
MRS/EX/MD/24/ VOL 01/0058	Sentai Guidewire Family	Sentai Guidewire Family	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -



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MRS/EX/MD/2 4/ VOL 01/0059	ORBERA365 Intragastric Balloon System	Boston Scietific	Boston Scientific South Africa PTY LTD	Apollo Endosurgery Inc.	27/05/2024	100 -
TRCMRS/EX/ MD/24/ VOL 01/0135	PTCA Dilatation Catheters	Emerge	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -
MRS/EX/MD/2 4/ VOL 01/0030	BIB Extraction Kit	Boston Scientific	Boston Scientific South Africa PTY LTD	Apollo Endosurgery Inc.	27/05/2024	100 -
TRCMRS/EX/ MD/24/ VOL 01/0133	Stingray™ LP Catheter	Stingray™ LP Catheter	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -
TRCMRS/EX/ MD/24/ VOL 01/0142	Stent System	SYNERGY	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -
MRS/EX/MD/2 4/ VOL 01/0056	Impulse™ Angiographic Catheters	Impulse™ Angiographic Catheters	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	27/05/2024	100 -



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TRCMRS/EX/MD/24/ VOL 01/0143	BIB Intra gastric Balloon System	Boston Scientific	Boston Scientific South Africa PTY LTD	Apollo Endosurgery Inc.	28/05/2024	100 -
TRCMRS/EX/MD/24/ VOL 01/0134	Urine DoA Cannabinoid Calibrators	Qauntilab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	29/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0165	DRI Cocaine Metabolite	Qauntilab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	29/05/2024	20 -
TRC/MRS/EX/MD/24/ VOL 01/0160	Fluid Pack	Qauntilab	Shiburi Distributors (PTY) ltd T/A Magnum Medical	Instrumentation Laboratory SpA	29/05/2024	200 -
TRC/MRS/EX/MD/24/ VOL 01/0161	Port Needle	PakuMed	Primedical Distributors Pty Ltd	PakuMed	24/06/2024	1000 -
TRC/MRS/EX/MD/24/ VOL 01/0178	AMS 3-PLY FACE MASK EAR LOOPED	AMS	PAK TRADING PTY LTD	AMS HEALTHCARE PTY LTD	04/07/2024	4000 -



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TRCMRS/EX/MD/24/ VOL 01/0100	Patient/Resident Shower Chair	Carino	Afmed (Pty) Ltd	ArjoHuntleigh AB	03/07/2024	50 -
TRC/MRS/EX/MD/24/ VOL 01/0159	Dispogel	Dispogel	Medswana (Pty) Ltd.	DISPOFARMA ILAC, SANAYI, VETCARE LTD STI	10/07/2024	120 -
MRS/EX/MD/24/ VOL 01/0009	MEDICAL EXAMINATION GLOVES TEXTURED NITRILE POWDERFREE GLOVES	ESP	FARRI INDUSTRIES PTY LTD	SRI TRANG GLOVES	12/07/2024	37360 -