



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
TRC/MRS/EX/M D/24/ VOL 01/0320	Ventana® HE 600	VENTANA HE 600 SYSTEM	Orthosurge Botswana Proprietary Limited	Ventana Medical Systems Inc.	03/09/2024	50 -
TRC/MRS/EX/M D/24/ VOL 01/0316	AED PLUS	ZOLL	CHUBBS BOTSWANA (PTY) LTD T/A JP BIOCHEM	Zoll Medical Cooperation- supplied by Stat Tiaken	03/09/2024	10 -
TRC/MRS/EX/M D/24/ VOL 01/0256	ANGIOGRAPHY CATHETER	KINDLY SHANGHAI MEDICAL CO LTD	Scientific medical & laboratory supplies	shanghai kindly medical instruments co ltd	03/09/2024	300 -
TRC/MRS/EX/M D/24/ VOL 01/0319	KIT COBAS 68/8800 MPXV I92T	KIT COBAS 68/8800 MPXV I92T	Orthosurge Botswana Proprietary Limited	Roche Molecular Systems, Inc.	04/09/2024	50 -
TRC/MRS/EX/M D/24/ VOL 01/0318	LightMix® Modular (FOR RESEARCH USE ONLY)	LightMix® Modular	Orthosurge Botswana Proprietary Limited	TIB MOLBIOL	05/09/2024	50 -



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TRC/MRS/EX/M D/24/ VOL 01/0331	Electrocardiograph, ambulatory, with analysis Algorithm	CARDEA SOLO	Paradigm Pharma pty(Ltd)	Dreamtech Co.Ltd	06/09/2024	10000 -
TRC/MRS/EX/M D/24/ VOL 01/0334	Endoform Antimicrobial Restorative Bioscaffold	Endoform	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0333	Endoform Natural Restorative Bioscaffold	Endoform	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0335	Myriad Matrix Soft Tissue Bioscaffold	Myriad Matrix	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -



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TRC/MRS/EX/M D/24/ VOL 01/0336	Myriad Morcells Fine	Myriad Morcells	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0333	Endoform Natural Restorative Bioscaffold	Endoform	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0334	Endoform Antimicrobial Restorative Bioscaffold	Endoform	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0335	Myriad Matrix Soft Tissue Bioscaffold	Myriad Matrix	Aesthetic Inclines T/A A.I. Health	AROA BIOSURGERY LTD.	12/09/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0328	Sorbact Gel Compress	Sorbact Gel Compress	Essity	ABIGO Medical AB	20/09/2024	40 boxes -



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TRC/MRS/EX/M D/24/ VOL 01/0322	Leukomed Sorbact	Leukomed Sorbact	Essity	ABIGO Medical AB	20/09/2024	12 boxes -
TRC/MRS/EX/M D/24/ VOL 01/0330	Cutimed® Sorbact® Swab	Cutimed® Sorbact® Swab	Essity	ABIGO Medical AB	20/09/2024	12 boxes -
TRC/MRS/EX/M D/24/ VOL 01/0348	IDEXX CatalystSmartQC * (SQC)	IDEXX CatalystSmartQC* (SQC)	IDEXX B.V.	IDEXX Distribution, Inc.	23/09/2024	100 -
TRC/MRS/EX/M D/24/ VOL 01/0323	Cutimed® Siltec® Sorbact® B and Sorbact® B Sacrum	Cutimed® Siltec® Sorbact®	Essity	ABIGO Medical AB	23/09/2024	12 boxes -
TRC/MRS/EX/M D/24/ VOL 01/0325	Cutimed® Sorbact® Dressing Pad	Cutimed® Sorbact®	Essity	ABIGO Medical AB	23/09/2024	12 boxes -



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TRC/MRS/EX/M D/24/ VOL 01/0329	Cutimed® Sorbact® Ribbon Gauze	Cutimed® Sorbact® Ribbon Gauze	Essity	ABIGO Medical AB	23/09/2024	12 boxes -
TRC/MRS/EX/M D/24/ VOL 01/0332	Cutimed Sorbion Sorbact	Cutimed Sorbion Sorbact	Essity	ABIGO Medical AB	23/09/2024	12 boxes -
TRC/MRS/EX/M D/24/ VOL 01/0363	Hemochron Signature Elite	Hemochron Signature Elite	Shiburi Distributors (PTY) Ltd T/A Magnum Medical	Accriva Diagnostic INC	04/10/2024	1500 -
TRC/MRS/EX/M D/24/ VOL 01/0365	BioMime™ - Sirolimus Eluting Coronary Stent System	BioMime™	Meril Life Sciences Pvt. Ltd.	Meril Life Sciences Private Limited	03/10/2024	2 of each size -



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TRC/MRS/EX/M D/24/ VOL 01/0366	MOZECTM- Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Balloon Dilatation Catheter	MOZECTM- Rapid Exchange Percutaneous Transluminal Coronary Angioplasty Balloon Dilatation Catheter	Meril Life Sciences Pvt. Ltd.	Meril Life Sciences Private Limited	04/10/2024	2 of each size -
TRC/MRS/EX/M D/24/ VOL 01/0368	PERSONAL ULTRASOUND SYSTEM (BUTTERFLY IQ/ IQ+ / IQ+	PERSONAL ULTRASOUND SYSTEM (BUTTERFLY IQ/ IQ+/ IQ+	Zebra Medical	Butterfly Network	09/10/2024	14 -



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TRC/MRS/EX/M D/24/ VOL 01/0372	Skore Nothing Strawberry Male Condom	Skore	POPULATION SERVICES INTERNATIONAL, SOUTH AFRICA	TTK Healthcare Limited – Protective Devices Division	10/10/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
TRC/MRS/EX/M D/24/ VOL 01/0374	Skore Zig Zag	Skore	POPULATION SERVICES INTERNATIONAL, SOUTH AFRICA	TTK Healthcare Limited – Protective Devices Division	10/10/2024	31104 condoms (10368 x packs of 3 condoms per pack) -



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TRC/MRS/EX/M D/24/ VOL 01/0370	Skore Nothing Climax Delay	Skore Condoms	POPULATION SERVICES INTERNATIONAL, SOUTH AFRICA	TTK Healthcare Limited – Protective Devices Division	15/10/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
TRC/MRS/EX/M D/24/ VOL 01/0367	Celox / Omni- stat Gauze PPH Haemostatic Devices	Celox PPH	Primedical Distributors Pty Ltd	Medtrade Products Ltd	15/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0375	Skore Time Less	Skore	POPULATION SERVICES INTERNATIONAL, SOUTH AFRICA	TTK Healthcare Limited – Protective Devices Division	15/10/2024	31104 condoms (10368 x packs of 3 condoms per pack) -



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TRC/MRS/EX/M D/24/ VOL 01/0373	Skore Skin Thin	Skore	POPULATION SERVICES INTERNATIONAL, SOUTH AFRICA	TTK Healthcare Limited – Protective Devices Division	15/10/2024	31104 condoms (10368 x packs of 3 condoms per pack) -
TRC/MRS/EX/M D/24/ VOL 01/0381	Stopcock 3way Extension Set (10cm and 100 cm)	BD	Becton Dickinson Pty Ltd	ZIBO QIAOSEND MEDICAL ARTICLES CO., LTD.	11/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0380	Stopcocks	BD Stopcocks and Manifolds	Becton Dickinson Pty Ltd	Sendal S.L., Almaraz, Spain	11/10/2024	1000 -



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TRC/MRS/EX/M D/24/ VOL 01/0378	Extension line low sorption (PE/PVC) length 150cm and 200 cm	Infusion extension lines	Becton Dickinson Pty Ltd	CAIR LGL	15/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0379	BD Pressure Rated Extension Sets	BD Pressure Rated Extension Sets	Becton Dickinson Pty Ltd	Sendal S.L., Almaraz, Spain	15/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0377	BD MaxZero™ clear needleless connector	MaxZero™ Needleless Connector	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	14/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0376	BD MaxPlus™ clear needleless connector	MaxPlus™ Needleless Connector	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	11/10/2024	1000 -



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TRC/MRS/EX/M D/24/ VOL 01/0349	BD SmartSite™ Bag Access Device. Needle- Free Valve	Access Devices	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	15/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0351	BD SmartSite™ Needle-Free Access Pin	Access Devices	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	15/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0359	BD MaxPlus™. MaxPlus™ extension set with clear needleless connector	Extension Sets	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	15/10/2024	1000 each -



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TRC/MRS/EX/M D/24/ VOL 01/0354	Alaris™ Products. SmartSite™ Needle-free System. INFUSION SET. FLOW CONTROLLER. VENTED. 15 µm FILTER.	Gravity Sets	Becton Dickinson Pty Ltd	CareFusion BH 335 d.o.o Cazin	15/10/2024	1000 each -
TRC/MRS/EX/M D/24/ VOL 01/0360	BD T-CONN W/LL & One Valve Port	Extension and Gravity Sets	Becton Dickinson Pty Ltd	Sistemas Medicos Alaris SA de C.V	18/10/2024	1000 -



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TRC/MRS/EX/M D/24/ VOL 01/0357	Alaris™ Products. SmartSite™ Needlefree System. TRANSFUSION/ BLOOD SET. UNVENTED. 200 Model Number 901-028E µm FILTER	Blood transfusion Set	Becton Dickinson Pty Ltd	CareFusion BH 335 d.o.o Cazin	18/10/2024	800 -
TRC/MRS/EX/M D/24/ VOL 01/0385	One Step HCG Pregnancy Test	Colloidal Gold	Dynamic Vitality(Pty)Ltd	Nantong Diagnos Biotechnology Co.Ltd	23/10/2024	3000 -



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TRC/MRS/EX/M D/24/ VOL 01/0021	Syntro-P Patient Home Monitoring and Wellbeing Application	Syntro-P Patient Home Monitoring and Wellbeing Application	BrandMed Management Services (Pty) Ltd	BrandMed Management Services (Pty) Ltd	28/10/2024	1 -
TRC/MRS/EX/M D/24/ VOL 01/0358	SmartSite Add-on Burette Set	BD Alaris Smartsite	Becton Dickinson Pty Ltd	Ningbo Hantech Medical Device Co., Ltd.	28/10/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0388	Disposable Latex Powdered Gloves	ESP	FARRI INDUSTRIES PTY LTD	BIOMAX	28/10/2024	45000 -
TRC/MRS/EX/M D/24/ VOL 01/0386	Exofin Fusion Skin Closure System 30cm	Chemence-exofin Fusion® Skin Closure System 30cm	Primedical Distributors Pty Ltd	Chemence Medical Inc	06/11/2024	1000 -



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TRC/MRS/EX/M D/24/ VOL 01/0261	Permanent Sled	Permanent Sled	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	12/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0257	Wolverine™ Coronary Cutting Balloon™ MONORAIL™ Microsurgical Dilatation Device	Wolverine™ Coronary Cutting Balloon™ MONORAIL™ Microsurgical Dilatation Device	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	11/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0234	Microcatheters	MAMBA	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	12/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0231	Guidezilla™ Guide Extension Catheter	Guidezilla™ Guide Extension Catheter	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	06/12/2024	500 -



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TRC/MRS/EX/M D/24/ VOL 01/0232	RunWay™ Guide Catheter	RunWay™ Guide Catheter	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	12/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0223	ROTAPRO Console	ROTAPRO Console	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	18/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0222	Rotablator Rotational Atherectomy System	Rotablator	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	12/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0233	PTCA Dilatation Catheter	NC Emerge™ PTCA Dilatation Catheter (MONORAIL)	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	18/11/2024	500 -



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TRC/MRS/EX/M D/24/ VOL 01/0228	Coronary Guidewires	ChoICE, ChoICE PT, PT Graphix, Mailman, Luge Guidewires ChoICE Magnet, ChoICE PT Magnet, PT Graphix Magnet, Mailman Magnet, Luge Magnet	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	11/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0260	Coronary Imaging Catheter	OptiCross™, OptiCross™6, OptiCross HD, OptiCross 6 HD	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	11/11/2024	500 -
TRC/MRS/EX/M D/24/ VOL 01/0478	LATEXEXAMTE XTUREPOWDE RGLOVES	ESP	FARRI INDUSTRIES PTY LTD	Sri Trang Gloves (Thailand) Co., Ltd.	19/11/2024	45000 -
TRC/MRS/EX/M D/24/ VOL 01/0371	1250-BSS EA-SOL 500ml plastic	Serumwerk	Envision Africa	Serumwerk Bernburg AG	21/11/2024	7200 -



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TRC/MRS/EX/M D/24/ VOL 01/0440	VC860301-OS 4 surgical platform, with HFDS glaucoma set, anterior/posterior with endo laser	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	12 -
TRC/MRS/EX/M D/24/ VOL 01/0420	500510- Ophthafutur Sil 5000 10ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	21/11/2024	1800 -
TRC/MRS/EX/M D/24/ VOL 01/0417	500503 - Ophthafutur Deca 7ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	21/11/2024	1800



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TRC/MRS/EX/M D/24/ VOL 01/0476	VV603210- Irrigation sleeve for incisions of 2.8-3.2 mm, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	5400 -
TRC/MRS/EX/M D/24/ VOL 01/0472	Caliburn trocar system 23G	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	722 -
TRC/MRS/EX/M D/24/ VOL 01/0477	OP-ES01-Eye Spear, 8 x 17mm	Cenefom Corp.	Envision Africa	Cenefom Corp.	21/11/2024	10000
TRC/MRS/EX/M D/24/ VOL 01/0468	VK400115-Laser probe OS 4, flexible curved, 25G, sterile/single use	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	10000 -



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TRC/MRS/EX/M D/24/ VOL 01/0474	VV300152- Chandelier illuminator bendable, 25G, with Caliburn trocar, snap lock for 23/25G, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	Box of 10 -
TRC/MRS/EX/M D/24/ VOL 01/0461	VV690101-Air delivery line with filter and 3-way stopcock, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	5400 units for 6 months. -



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TRC/MRS/EX/M D/24/ VOL 01/0475	VV300194-Endo illuminator panorama, 23G, shielded, with ViPer scleral indenter, comfort- connector, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	7200 -
TRC/MRS/EX/M D/24/ VOL 01/0463	VV803100-Test chamber for phaco, silicone, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	22/11/2024	1080 -
TRC/MRS/EX/M D/24/ VOL 01/0438	SC23.D01-23G Scissors Vertical	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	25/11/2024	23 -



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TRC/MRS/EX/M D/24/ VOL 01/0437	LP23.A05-23G 90° Directional Illumin Laser Probe	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	25/11/2024	1200 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0439	SC23.D03-23G Scissors Horizontal Curved	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	25/11/2024	900 -
TRC/MRS/EX/M D/24/ VOL 01/0465	VE904705- Sterilization container with tray, plastic (249 x 148 x 47 mm)	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	25/11/2024	24 -



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TRC/MRS/EX/M D/24/ VOL 01/0462	VV66001 ID- Phaco pack OS 4: cassette, easyTip 2.2 mm 40°, irrigation sleeve, phaco key, emergency key, test chamber, infusion set, display cover, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	25/11/2024	10000 -
TRC/MRS/EX/M D/24/ VOL 01/0422	500514- Ophthafutur C3F8 15ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	25/11/2024	1800 -



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TRC/MRS/EX/M D/24/ VOL 01/0421	500512- Ophthafutur SF6 15ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	26/11/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0425	Balanced Salt solution	Serumwerk	Envision Africa	Serumwerk Bernburg AG	26/11/2024	7200 -
TRC/MRS/EX/M D/24/ VOL 01/0418	500508 - Ophthafutur Sil 1000 10ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	26/11/2024	1800 -
TRC/MRS/EX/M D/24/ VOL 01/0423	500513- Ophthafutur C2F6 15ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	26/11/2024	1800 -



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TRC/MRS/EX/M D/24/ VOL 01/0470	VV106110- Continuous Flow Cutter 23G, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	10000 -



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TRC/MRS/EX/M D/24/ VOL 01/0473	VV806840-Phaco tip easyTip 2.8 mm, 30°, with irrigation sleeve, test chamber, phaco key, emergency key, for incisions of 2.8-3.2 mm, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	7200 -



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TRC/MRS/EX/M D/24/ VOL 01/0471	VV806835A- Phaco tip easyTip 2.2 mm, 30°, with irrigation sleeve, test chamber, phaco key, emergency key, for incisions of 2.2-2.4 mm, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	7200 -



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TRC/MRS/EX/M D/24/ VOL 01/0469	VV104110- Continuous Flow Cutter 20G, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	10000 -
TRC/MRS/EX/M D/24/ VOL 01/0466	VG800011- easyPhaco handpiece, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	24 -
TRC/MRS/EX/M D/24/ VOL 01/0419	500509 - Ophthafutur Sil 2000 10ml Syringe	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	26/11/2024	1800 -
TRC/MRS/EX/M D/24/ VOL 01/0435	FC23.D05-23G Forceps Eckardt Endgripping	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	26/11/2024	2400 units for 6 months -



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TRC/MRS/EX/M D/24/ VOL 01/0441	VE201712- Diathermy handpiece, short, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	26/11/2024	12 -
TRC/MRS/EX/M D/24/ VOL 01/0424	OFHPMC2- OphthaFutur HPMC 2% 2ml	Pharmpur GmbH	Envision Africa	Pharmpur GmbH	26/11/2024	1800 -
TRC/MRS/EX/M D/24/ VOL 01/0443	VE201722- Diathermy tip Eraser, 50° beveled, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	12 units for 6 months -
TRC/MRS/EX/M D/24/ VOL 01/0432	MV018-Alsavisc 1.8% 1.1ml	Alsanza Medizintechnik & Pharma GmbH	Envision Africa	Alsanza Medizintechnik & Pharma GmbH	27/11/2024	3600 units for 6 months. -



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TRC/MRS/EX/M D/24/ VOL 01/0384	Everolimus- Eluting Platinum Chromium Coronary Stent System	SYNERGY™ SHIELD MONORAIL™	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation 300 Boston Scientific Way Marlborough MA 01752 USA	27/11/2024	1000 -



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Application/ Letter Reference Number	Product Name	Model Name /Number/ Brand Name	Applicant Details	Manufacturer Details	Date of Approval	Quantity Approved
TRC/MRS/EX/M D/24/ VOL 01/0456	VV660011AE- Phaco pack OS 4: cassette, easyTip 2.8 mm 30°, irrigation sleeve, phaco key, emergency key, test chamber, infusion set, display cover, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	10 000 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0395	derma+flex®	Chemence	Primedical Distributors Pty Ltd	Chemence Medical Inc	27/11/2024	10000 -



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
TRC/MRS/EX/M D/24/ VOL 01/0454	VV660010- Cassette for OS 4, with infusion set and display cover, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	10 000 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0428	VV660213BP- Vitrectomy pack OS 4 23G: cassette, CF cutter, endo illuminator panorama with ViPer scleral indenter, Caliburn trocar system, air delivery line with 3-way stopcock, infusion set, display cover, sterile/single use, box of 6	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	4800 units for 6 months -



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
TRC/MRS/EX/M D/24/ VOL 01/0453	VV603220- Irrigation sleeve for incisions of 2.2-2.4 mm, silicone, transparent, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	7200 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0436	FC23.D03-23G Forceps ILM Endgripping	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	27/11/2024	2400 -
TRC/MRS/EX/M D/24/ VOL 01/0433	EASOS-Silicone Oil System	Envision Africa (Pty) Ltd	Envision Africa	Envision Africa (Pty) Ltd	27/11/2024	2400 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0457	VV662006-Active infusion set for OS 4, sterile/single use, box of 6	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	3600 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0480	Exofin	Chemence	Primedical Distributors Pty Ltd	Chemence Medical Inc	27/11/2024	10000 -
TRC/MRS/EX/M D/24/ VOL 01/0442	VE201726- Capsulotomy tip, standard, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	12 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0426	MVR20A-MVR - 1.2mm 20G, Angled	Shah Eye Care (Pty) Ltd	Envision Africa	Shah Eye Care (Pty) Ltd	27/11/2024	2400 units for 6 months -



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
TRC/MRS/EX/M D/24/ VOL 01/0449	VE65525-I/A Quick Tip for use with irrigation sleeve, 45°, aspiration port 0.25 mm, leg- length 1.5 mm, for incisions of 2.2-3.2 mm, safety design, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	27/11/2024	12 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0434	BF23.D01-23G Blunt Backflush Instrument	Beaver - Visitec International Ltd	Envision Africa	VitreQ B.V.	27/11/2024	2700 units for 6 months -
TRC/MRS/EX/M D/24/ VOL 01/0450	VE860001- Instrument table for OS 4	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	28/11/2024	12 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0458	VV690340- Universal visco cannula for Caliburn trocar system 23/25/27G, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	29/11/2024	1080 -



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
TRC/MRS/EX/M D/24/ VOL 01/0459	VV690350- Silicone injection/extraction set, 10 cc, with universal visco cannula for Caliburn trocar system 23/25/27G, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	29/11/2024	7200 -
TRC/MRS/EX/M D/24/ VOL 01/0452	VE203902- Diathermy forceps bipolar, curved, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	29/11/2024	12 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0431	MV013-Alsavis 1.6% 1.1ml	Alsanza Medizintechnik & Pharma GmbH	Envision Africa	Alsanza Medizintechnik & Pharma GmbH	29/11/2024	3600 -
TRC/MRS/EX/M D/24/ VOL 01/0484	Filmogen liquid bandage	Pileseptin	Delta Pharmaceuticals Pty Ltd	Hetero Labs Limited Unit-III,	29/11/2024	1000 -
TRC/MRS/EX/M D/24/ VOL 01/0396	CATHETER FOELY DISPOSABLE CH	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	34800 -
TRC/MRS/EX/M D/24/ VOL 01/0411	SURGICAL MASK	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	1000 PACK OF 50 -
TRC/MRS/EX/M D/24/ VOL 01/0409	DISPOSABLE SYRINGES	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	8840 PACK OF 100 -



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
TRC/MRS/EX/M D/24/ VOL 01/0400	CUFFED ENDOTRACHEA L TUBE	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	9600 -
TRC/MRS/EX/M D/24/ VOL 01/0412	WOODEN TOUNGE DEPRESSOR	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	600 -
TRC/MRS/EX/M D/24/ VOL 01/0414	THEATER MOP CAPS	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	600 PACK OF 100 -
TRC/MRS/EX/M D/24/ VOL 01/0403	FIRST AID KIT	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	400 -
TRC/MRS/EX/M D/24/ VOL 01/0413	ZINC OXIDE PLASTERS	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	6000 ROLLS -



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
TRC/MRS/EX/M D/24/ VOL 01/0410	SURGICAL BLADE	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	400 -
TRC/MRS/EX/M D/24/ VOL 01/0405	IV CANNULA	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	200000 PCS -
TRC/MRS/EX/M D/24/ VOL 01/0408	PARAFFIN GAUZE	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	1000 PACK OF 10 -
TRC/MRS/EX/M D/24/ VOL 01/0404	GAUZE BANDAGES	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	3200 -
TRC/MRS/EX/M D/24/ VOL 01/0402	DISPOSABLE HYPODERMIC NEEDLES	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	4000 PACK OF 100 -



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
TRC/MRS/EX/M D/24/ VOL 01/0407	OXYGEN MASK	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	2000 -
TRC/MRS/EX/M D/24/ VOL 01/0393	BLOOD TRANSFUSION SET 20DROPS	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	4000 -
TRC/MRS/EX/M D/24/ VOL 01/0392	ABSORBENT COTTON WOOL 500GM	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	600 -
TRC/MRS/EX/M D/24/ VOL 01/0406	IV GIVING SET	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	22000 PCS -
TRC/MRS/EX/M D/24/ VOL 01/0401	DISPOSABLE LATEX EXAM GLOVES	HEUER	International Pharmaceutical Alliance	GST CORPORATION LTD	02/12/2024	15500 PACK OF 100 -



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
TRC/MRS/EX/M D/24/ VOL 01/0485	Inogen One G5	Inoogen	Kalahari Medical Distributors	INOGEN INC	04/12/2024	3 -
TRC/MRS/EX/M D/24/ VOL 01/0231	Guidezilla™ Guide Extension Catheter	Guidezilla™ Guide Extension Catheter	Boston Scientific South Africa PTY LTD	Boston Scientific Corporation	06/12/2024	500 -



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
TRC/MRS/EX/M D/24/ VOL 01/0464	VV806835-Phaco tip easyTip 2.2 mm, 40°, with irrigation sleeve, test chamber, phaco key, emergency key, for incisions of 2.2-2.4 mm, sterile/single use, box of 10	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	22/11/2024	7200 -
TRC/MRS/EX/M D/24/ VOL 01/0494	Automatic Chemiluminescence Immunoassay System	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co., Ltd.	17/12/2024	88 -



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
TRC/MRS/EX/M D/24/ VOL 01/0492	Automatic Nucleic Acid Extraction System	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co., Ltd.	19/12/2024	10 -
TRC/MRS/EX/M D/24/ VOL 01/0445	VE201733-Endo diathermy tip 23G, 54° pointed, cannula length 28 mm, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	19/12/2024	12 -
TRC/MRS/EX/M D/24/ VOL 01/0446	VE201751-HFDS glaucoma tip, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	19/12/2024	12 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0444	VE201732-Endo diathermy tip 25G, 54° pointed, cannula length 28 mm, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	19/12/2024	12 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0448	VE655000-I/A handpiece, coaxial, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	19/12/2024	12 units -
TRC/MRS/EX/M D/24/ VOL 01/0460	VV800051-Endo phaco tip 20G, 15°, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	19/12/2024	24 units for 6 months. -



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
TRC/MRS/EX/M D/24/ VOL 01/0447	VE654101-I/A bimanual instrument set, roughened tips, diameter 0.8 mm, aspiration port 0.3 mm, irrigation port 0.5 mm, safety design, reusable	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	20/12/2024	12 -
TRC/MRS/EX/M D/24/ VOL 01/0451	VE860010-Dual- linear, wireless pedal for OS 4	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	20/12/2024	12 units for 6 months. -
TRC/MRS/EX/M D/24/ VOL 01/0491	BK-280 Fully Auto Chemistry Analyze	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co.,	20/12/2024	138 -



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
TRC/MRS/EX/M D/24/ VOL 01/0488	BK-280 Reagents Controls, Calibrators, Chemistry Reagents and Consumables	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co., Ltd.	20/12/2024	71 -
TRC/MRS/EX/M D/24/ VOL 01/0490	BK-CA04 Blood Coagulation Analyzer	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co., Ltd.	20/12/2024	40 Packages -
TRC/MRS/EX/M D/24/ VOL 01/0467	VK400103-Laser probe OS 4, flexible curved, 23G, sterile/single use	Oertli Instruments AG	Envision Africa	Oertli Instruments AG	21/11/2024	10000 -



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
TRC/MRS/EX/M D/24/ VOL 01/0487	BK-6310 5-Part Auto Hematology Analyzer	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co.,	20/12/2024	20 -
TRC/MRS/EX/M D/24/ VOL 01/0493	Microbiology Laboratory Microbial ID and AST System	BIOBASE	M.I Clinic Proprietary Limited	Biobase Biodustry (Shandong) Co.,	20/12/2024	30 -
TRC/MRS/EX/M D/25/ VOL 01/0001	Carino	ArjoHuntleigh AB	Afmed (Pty) Ltd	ArjoHuntleigh AB	08/01/2025	1 -