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TITLE: HUMAN MEDICAL DEVICES INCLUDING IN VITRO DIAGNOSTICS REGISTER

No	Registration Number/Notification Number	Medical Device's Brand name	Medical Device's Generic name	Class of the medical device	Pack size	Shelf life	Manufacturer's name	Address of the Manufacturer	Marketing Authorization Holder/ Applicant	Marketing Authorization Holder's/ Applicant's country	Local Technical Representative (LTR)	Registration Date	Expiration Date
1	0541/Rwanda FDA/2019	ORAQUICK® HIV SELF-TEST	HIV 1/2 Rapid Antibody Test	Class D, IVD	5X4-1000: 50T/kit; 5X4-1001: 250T/kit; 5X4-2001: 110T/kit	30 Months	Site 1: OraSure Technologies, Inc Site 2: Pacific Biotech Co., Ltd. Site 3: Pacific Biotech Co., Ltd.	Site 1: Inc, 220 East First Street, Bethlehem, PA, 18015-1360, USA Site 2: 42M004 Phetchabun Chalianglub Rd., Napa, Muang, Petchabun 6700, Thailand. Site 3: Pacific Biotech Co., Ltd. 137 Moo 1 General Industrial Zone Hi-Tech Industrial Estate Banlane, Bangpa-In Ayutthaya 13160 Thailand	OraSure Technologies, Inc	USA	Vine Pharma Limited	14/05/2019	13/05/2024
2	Rwanda FDA-MDP-MA-0001	Pima™ CD4	CD4 test	Class C, IVD	100 cartridges (260100100) or 25 cartridges (260100025)	18 Months	Abbott Rapid Diagnostics Jena GmbH (Germany)	Orlaweg 1, D-07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027
3	Rwanda FDA-MDP-MA-0002	Panbio COVID 19 Ag rapid test device (nasal)	COVID test	Class D, IVD	25 Tests (product code 41FK11), 25 tests (product code	24 Months	Abbott Diagnostics Korea Inc	65, Borahagal-ro, Giheung-gu Yongin-si,	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027

					41FK21)			Gyeonggi-do 17099, Republic of Korea					
4	Rwanda FDA- MDP-MA-0003	Determine™ HIV Early Detect	HIV test	Class D, IVD	20 Tests (product code 7D2842), 100 tests (product code 7D2843), 100 tests (product code 7D2843SET	18 Months	Abbott Diagnostics Medical Co., Ltd. Chiba Plant	Chiba Plant, 357 Matsuhidia, Matsudo-shi, Chiba, 270-2214, Japan	Abbott Diagnostics Medical Co., Ltd.	Japan	MNR East Africa Ltd	30/12/2022	29/12/2027
5	Rwanda FDA- MDP-MA-0004	Determine™ Syphilis TP	Syphilis test	Class C, IVD	30 tests (product code: 7D2442) or 100 tests (product code: 7D2443)	15 Months	Abbott Diagnostics Medical Co., Ltd.,Japan	Chiba Plant, 357 Matsuhidia, Matsudo-shi, Chiba, 270-2214, Japan	Abbott Diagnostics Medical Co., Ltd.	Japan	MNR East Africa Ltd	30/12/2022	29/12/2027
6	Rwanda FDA- MDP-MA-0005	Panbio™ COVID 19 Ag Rapid Test Device (Nasopharyngeal)	COVID test	Class D, IVD	25 Tests (product code 41FK10), 25 tests (product code 41FK20)	24 Months	Abbott Diagnostics Korea Inc	65, Borahagal-ro, Giheung-gu Yongin-si, Gyeonggi-do 17099, Republic of Korea	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027
7	Rwanda FDA- MDP-MA-0006	m-PIMA™ Analyser	Analyser for HIV-1/2 detection	Class D, IVD	W20cm x H22cm x D31 cm, 8kg with the m-PIMA Analyser box (400 x 300 x 410 mm)	N/A	Abbott Rapid Diagnostics Jena GmbH, Germany	Orlaweg 1, D- 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027
8	Rwanda FDA- MDP-MA-0007	m-PIMA HIV- 1/2 Detect	HIV 1/2 test	Class D, IVD	10 x Cartridge Kit (product code 27011R010), 50 x Cartridge Kit (product code 27011R050)	9 Months	Abbott Rapid Diagnostics Jena GmbH, Germany	Orlaweg 1, D- 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027
9	Rwanda FDA- MDP-MA-0008	m-PIMA HIV- 1/2 VL	HIV 1/2 VL test	Class C, IVD	50 Cartridge Kit (product code 27015-W50)	10.7 Months	Abbott Rapid Diagnostics Jena GmbH, Germany	Orlaweg 1, D- 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	30/12/2022	29/12/2027
10	Rwanda FDA- MDP-MA-0009	Determine™ HBsAg 2	HBsAg 2 Test	Class D, IVD	20 Tests (product code 7D2942), 100 tests (product code 7D2943), 100 tests (product code 7D2943SET)	18 Months	Abbott Diagnostics Medical Co., Ltd., Japan	Chiba Plant, 357 Matsuhidia, Matsudo-shi, Chiba, 270-2214, Japan	Abbott Diagnostics Medical Co., Ltd	Japan	MNR East Africa Ltd	30/12/2022	29/12/2027
11	Rwanda FDA- MDP-MA-0010	Yumizen G400 DDi	Hemostasis Analyzer	Class B, Medical Device	1 box contains one Yumizen G400	N/A	Horiba ABX SAS,	Parc Euromédecine, Rue du Caducée - BP7290, 34184 Montpellier Cedex 4, France	Horiba ABX SAS	France	Medisell Rwanda Ltd	31/03/2023	30/03/2028
12	Rwanda FDA- MDP-MA-0011	Pima Analyser	Cytometry Analyser	Class C, IVD	1 box X Pima Analyser	N/A	Abbott Rapid Diagnostics Jena GmbH, Germany	Orlaweg 1, 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	31/03/2023	30/03/2028
13	Rwanda FDA- MDP-MA-0012	Pima™ Bead Standard	External Quality Control	Class C, IVD	1 box containing one “Low” and one “Normal” control	24 Months storage stability and	Abbott Rapid Diagnostics Jena GmbH,	Orlaweg 1, 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	31/03/2023	30/03/2028

			material		cartridge	6 months in-use stability (upon opening)	Germany						
14	Rwanda FDA-MDP-MA-0013	Clean Cart C	Citric acid preparation for hemodialysis system cleaning	Class A, Medical device	Each Clean Cart C cartridge contains a minimum of 32 grams of citric acid anhydrous powder	24 Months	Gambro Dasco S.p.A,	Via Modenese 66- 41036-Medolla (MO), Italy	Baxter AG Scientific	Egypt	Africa Healthcare Network	31/03/2023	30/03/2028
15	Rwanda FDA-MDP-MA-0014	ADE M321600 electronic mother and child scale	Electronic scale	Class A, Medical Device	1box X scale, ABS plastic	N/A	ADE Germany GmbH, Germany	Neuer Holtighbaum, 22143 Hamburg, Germany	ADE Germany GmbH & Co.K,	Germany	Medisell Rwanda Ltd	31/03/2023	30/03/2028
16	Rwanda FDA-MDP-MA-0015	Cidex™ Instrument Tray System	Cleaning and disinfecting fluid container	Class A, Medical Device	1 Package X Instrument Tray System, Package Total Capacity (3.6 L/1.0 Ga, 8.1 L/2.1 Gal, 14.1 L/3.7 Gal, 17.5 L/4.6 Gal. and 19.8 L/5.2 Gal)	N/A	Hi-Tech Mold and Tool, Inc., USA	1 Technology Drive West Pittsfield, MA 01201, USA	Advanced sterilization products Inc.	USA	Pyramid Pharma Limited	31/03/2023	30/03/2028
17	Rwanda FDA-MDP-MA-0016	CIDEX™ OPA Solution Test Strips	Chemical indicator	Class A, Medical Device	15 Strips/Bottle, 2 Bottles/Shipper and 60 Strips/Bottle, 2 Bottles/Shipper	10 Months for closed bottles & 90 days after opening the bottle	Albert Browne Ltd, United Kingdom	Chancery House, Rayns Way, Watermead Business Park, Syston, Leicester, LE7 1PF, United Kingdom	ASP International GmbH Zweigniederlassung Zug,	Switzerland	Pyramid Pharma Limited	31/03/2023	30/03/2028
18	Rwanda FDA-MDP-MA-0017	DORA Tubing Sets for Hemodialysis	Blood tubing set	Class B, Medical Device	1 pack contains 2 tubing sets for hemodialysis	36 Months	Bain medical equipment (Guangzhou) Co., Ltd, P.R China	No.10. Juncheng Road, Eastern Area, 510760 Guangzhou, P.R China	Bain medical equipment (Guangzhou) Co., Ltd,	P.R China.	Africa Healthcare Network	31/03/2023	30/03/2028
19	Rwanda FDA-MDP-MA-0018	DORA Disposable A.V fistula needle sets	AV Fistula needles	Class B, Medical Devices	14G, 15G, 16G and 17G	36 Months	Bain medical equipment (Guangzhou) Co., Ltd, P.R China	No.10. Juncheng Road, Eastern Area, 510760 Guangzhou, P.R China	Bain medical equipment (Guangzhou) Co., Ltd,	P.R China.	Africa Healthcare Network	31/03/2023	30/03/2028
20	Rwanda FDA-MDP-MA-0019	CheckNOW™ HIV Self-Test	HIV test	Class D, IVD	For Individual test devices: 145x70 mm; PET12/A17/ CPP55; Kit: 215x140 mm; PET12/PE40	24 Months	Abbott Rapid Diagnostics Jena GmbH	Orlaweg 1 07743 Jena, Germany	Abbott Rapid Diagnostics Jena GmbH	Germany	MNR East Africa Ltd	19/07/2023	18/07/2028
21	Rwanda FDA-MDP-MA-0020	9180 Electrolyte Analyzer	Electrolyte Analyzer	Class B, IVD	HxWxD: 33.5x31.5x29.5 cm (13.2x12.4x12.0 in)	Not Applicable	Roche Diagnostics GmbH	Sandhofer Strasse 116,68305 Mannheim, Germany	Roche Kenya Limited	Kenya	Medisell Rwanda Ltd	19/07/2023	18/07/2028
22	Rwanda FDA-MDP-MA-0021	Clean Cart A	Sodium Carbonate	Class A Medical device	33x13g	24 Months	Gambro Dasco S.p.A	Via Modenese 66- 41036-Medolla (MO), Italy	Baxter AG Scientific Office	Egypt	Africa Healthcare Network	19/07/2023	18/07/2028

23	Rwanda FDA-MDP-MA-0022	Novaplume Disposable AV Fistula Needle Sets	Fistula Needle Set	Class B, Medical Devices	G14, G15, G16, G17	36 Months	Bain Medical Equipment (Guangzhou) Co., Ltd	No.10 Juncheng Road, Eastern Area, Economic & Technological Development District, Guangzhou, 510760, China	Baxter AG Scientific Office	Egypt	Africa Healthcare Network	19/07/2023	18/07/2028
24	Rwanda FDA-MDP-MA-0024	Cidezyme Enzymatic Detergent	Enzymatic Detergent	Class A	1 Liter Bottle, 12 Bottles/Shipper; 5 Liter Bottle, 4 Bottles/Shipper	24 Months	Advanced Sterilization Products Inc.	33 technology drive, Irvine, CA 92618, USA	Advanced Sterilization Products Inc.	USA	Pyramid Pharma Limited	10/12/2023	09/12/2028
25	Rwanda FDA-MDP-MA-0025	Yumizen G200	Hemostasis Analyzer	Class B	5.0x10.2x16.5 cm (HxWxD)	Not Applicable	HORIBA ABX SAS, DIAGON	Parc Euromédecine Rue du Caducée - BP7290, 34184 Montpellier Cedex 4 France (OBL); Baross u. 48-52. Budapest, H-1047; Hungary and DIAGON, GZO-Zukunftsweg 1.; Siegendorf ; A-7011 ; Austria (OEM)	HORIBA ABX SAS	France	Medisell Rwanda Ltd	10/12/2023	09/12/2028
26	Rwanda FDA-MDP-MA-0026	Yumizen H2500	Hematology Analyzer	Class B	Yumizen H2500: 870x670x730 mm, Yumizen H2500 + CIM: 870x990x730 mm	Not Applicable	HORIBA ABX SAS	Parc Euromédecine Rue du Caducée, BP7290, 34184 Montpellier Cedex 4 France	HORIBA ABX SAS	France	Medisell Rwanda Ltd	10/12/2023	09/12/2028
27	Rwanda FDA-MDP-MA-0027	Yumizen H500 OT/CT	Hematology Analyzer	Class B, IVD	397x477x483 mm (WxDxH)	Not Applicable	HORIBA ABX SAS	Parc Euromédecine Rue du Caducée, BP7290, 34184 Montpellier Cedex 4 France	HORIBA ABX SAS	France	Medisell Rwanda Ltd	10/12/2023	09/12/2028
28	Rwanda FDA-MDP-MA-0028	Yumizen H550	Hematology Analyzer	Class B, IVD	53x66.8x62.1cm (WxDxH)	Not Applicable	HORIBA ABX SAS,	Parc Euromédecine Rue du Caducée, BP7290, 34184 Montpellier Cedex 4 France	HORIBA ABX SAS	France	Medisell Rwanda Ltd	10/12/2023	09/12/2028
29	Rwanda FDA-MDP-MA-0029	Arterial Venous Fistula Needle (AVF set)	Fistula Needle Set	Class B, Medical Device	16G (1.60mm), 17G (1,40mm), 50 Pieces per box	60 Months	Nipro (Thailand) corporation Limited	10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110, Thailand	Nipro middle East FZE	UAE	Africa healthcare network, Rwanda	10/12/2023	09/12/2028

30	Rwanda FDA-MDP-MA-0030	NIPRO Blood tubing set	Blood Tubing Set	Class B, Medical Device	OD: 520x430x250 mm, ID: 508x418x226 mm, SD:516x426x241 mm (LxHxH), Packed in KA230/3CA125/K A230, BC flute	60 Months	Nipro (Thailand) corporation Limited, and Nipro JMI Company Ltd	10/2 Moo 8 Bangnomko, Sena, Phra Nakhon Si Ayutthaya 13110, Thailand; Holding 72/C, Progoti Shoroni, Middle Badda, 1212 Dhaka, Bangladeshi.	Nipro middle East FZE	UAE	Africa healthcare network, Rwanda	10/12/2023	09/12/2028
31	Rwanda FDA-MDP-MA-0031	Enteral Feeding Tubes- Penta Enteral	Enteral Feeding Tubes	Class B, Medical Device	Nasogastric tubes are packed 40 or 50 pieces /box, syringes of 10 ml are packed 100 pieces/ box and syringes of 20 ml are packed 80 pieces/ box	60 Months	Becton Dickinson India Pvt. Ltd	Plot No.1, Sector-3, IMT, Bawal, District Rewari Haryana – 123501, India	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
32	Rwanda FDA-MDP-MA-0032	BD SoloShot™ Mini	Syringe	Class B, Medical Device	100 or 200 syringes per shelf carton	60 Months	Becton Dickinson India Pvt. Ltd	Plot No.1, Sector-3, IMT, Bawal, District Rewari Haryana – 123501, India	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
33	Rwanda FDA-MDP-MA-0033	BD Arterial Cannula	Arterial Cannula	Class B	BD arterial cannula with flows switch is 20g	60 Months	Becton Dickinson Infusion Therapy Inc.	9450 South State Street Sandy, Utah 84070, USA	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
34	Rwanda FDA-MDP-MA-0034	BD PhaSeal System	Drug Transfer Device	Class B, Medical Device	1 box contains BD PhaSeal drug Transfer Device	30 to 60 Months	Becton Dickinson and Company Limited,	Pottery Road, Dun Laoghaire, Co.Dublin, Ireland	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
35	Rwanda FDA-MDP-MA-0035	Alaris GW infusion sets	Infusion set	Class B	Standard Alaris GW infusion set is packaged in a pouch that measures approximately 6 inches by 4 inches, with a thickness of less than 1 inch	24 to 60 Months	BD Switzerland Sàrl,	Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
36	Rwanda FDA-MDP-MA-0036	Alaris GP Infusion sets	Infusion Set	Class B	Carton of 50 units with Set length of 250cm	24 to 36 Months	BD Switzerland Sàrl,	Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028
37	Rwanda FDA-MDP-MA-0037	Alaris Extension Sets	Extension set	Class B	Peel pack 100x120 mm	36 Months	BD Switzerland Sàrl,	Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, 1262 Eysins Switzerland	Becton Dickinson East Africa Limited	Kenya	Biopharmacia Company Limited	10/12/2023	09/12/2028

38	Rwanda FDA-MDP-MA-0038	Cobas c 311	Clinical Chemistry Analyzer	Class B	134 X 86 X 126 with weight of 270 Kg	60 Months	ROCHE Diagnostics GmbH;	Sandhofer Strasse 116, Mannheim, Germany, 68305	Roche Kenya Limited	Kenya	Medisell Rwanda Ltd	10/12/2023	09/12/2028
39	Rwanda FDA-MDP-MA-0039	Ventana DP 200 Slide scanner	Slide Scanner	Class B, IVD	49.8 cm x 67.8 cm x 46.2 cm (WxDxH)	Not Applicable	FFEI Ltd	The Cube, Maylands Avenue, Hemel Hempstead, Hertfordshire, HP2 7DF, United Kingdom	Roche Kenya Limited	Kenya	Medisell Rwanda Ltd	10/12/2023	09/12/2028
40	Rwanda FDA-MDP-MA-0040	Determine TB LAM Ag	TB LAM Ag Test	Class C, IVD	5 cards (5 tests/card) per kit	17 Months	Abbott Diagnostics Scarborough, Inc.	10 Southgate Road, Scarborough, Maine 04074, USA	Abbott Diagnostics Scarborough, Inc.	USA	MNR East Africa Limited	10/12/2023	09/12/2028
41	Rwanda FDA-MDP-MA-0041	Panbio™ COVID-19 Antigen Self-Test	COVID-19 Antigen Test	Class D, IVD	1,4,10 or 20 Tests per Kit	24 Months	Abbott Diagnostics Korea Inc.	65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, 17099 Country: Republic of Korea	Abbott Rapid Diagnostics Jena GmbH,	Germany	MNR East Africa Limited	10/12/2023	09/12/2028

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