



**RWANDA FDA**  
Rwanda Food and Drugs Authority

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**RWANDA FDA AUTHORIZATION FOR EMERGENCY USE PRODUCTS-SEPTEMBER 2021**

S/N	REGISTRATION NO.	PRODUCT BRAND NAME	ACTIVE PHARMACEUTICAL INGREDIENTS	DOSAGE STRENGTH	DOSAGE FORM	PRODUCT CATEGORY	PACK SIZE	PACKAGING TYPE	SHELF LIFE	MANUFACTURER	MANUFACTURER COUNTRY	MARKET AUTHORIZATION HOLDER (MAH)	LOCAL TECHNICAL REPRESENTATIVE-LTR	APPROVAL DATE
1	RWANDA FDA-AEU- 0001/2021	BAMKANIVIMAB	BAMLANIVIMAB	700 MG/20 ML	SOLUTION FOR INTRAMUSCULAR INJECTION	HUMAN	1 VIAL OF 20ML PER BOX	TYPE I GLASS VIAL CLOSED BY CHLOROBUTYL ELASTOMERIC STOPPER AND SEALED BY POLYPROPYLENE/ALUMINUM FLIP-TOP SEAL	12 MONTHS	ELI LILLY AND COMPANY	USA	ELI LILLY (SA) (PTY) LIMITED	N/A	18/02/2021
2	RWANDA FDA-AEU- 0002/2021	COMIRNATY®	TOZINAMERAN	30 MICROG OF RNA IN 0.3ML	WHITE TO OFF-WHITE FROZEN DISPERSION FOR INTRAMUSCULAR INJECTION (STERILE CONCENTRATE).	HUMAN	2 ML GLASS VIAL	2 ML CLEAR MULTIDOSE VIAL (TYPE I GLASS) WITH A STOPPER (SYNTHETIC BROMOBUTYL RUBBER) AND A FLIP-OFF PLASTIC CAP WITH ALUMINIUM SEAL.	6 MONTHS (UNOPENED VIAL)	BIONTECH MANUFACTURING GMBH	GERMANY	PFIZER EUROPE MA EEIG	N/A	1/3/2021
3	RWANDA FDA-AEU- 0003/2021	COVISHIELD™	CHADOX1-S RECOMBINANT	5 X 10 <sup>10</sup> VIRAL PARTICLES (VP)	SOLUTION FOR INJECTION	HUMAN	2 DOSE – VIAL, 10 DOSE – VIAL	2ML CLEAR TUBULAR USP TYPE 1 (D16.5MM × H30MM), 5ML CLEAR TUBULAR USP TYPE 1 (D16.5MM × H52 MM).	6 MONTHS AT 2°C – 8°C	SERUM INSTITUTE OF INDIA PRIVATE LIMITED	INDIA	SERUM INSTITUTE OF INDIA PRIVATE LIMITED	N/A	19/02/2021
4	RWANDA FDA-AEU- 0004/2021	COVID-19 VACCINE ASTRAZENECA	CHADOX1-S RECOMBINANT	5 X 10 <sup>10</sup> VIRAL PARTICLES (VP)	SOLUTION FOR INJECTION	HUMAN	10 DOSES PER VIAL, 10 VIALS/BOX	CLEAR AND COLORLESS VIALS, CLOSED WITH ELASTOMERIC STOPPERS, AND SEALED WITH ALUMINUM OVER SEALS IN A CARTON	6 MONTHS AT 2°C – 8°C UNOPENED	SK BIOSCIENCE CO. LTD (SK BIO)	REPUBLIC OF KOREA	ASTRAZENECA AB	N/A	23/02/2021
5	RWANDA FDA-AEU- 0005/2021	GAM-COVID-VAC	COVID-19, (COMPONENT I + COMPONENT II)	0.5 ML/DOSE CONTAINING (1.0±0.5) X 1.0 <sup>11</sup> PARTICLES	SOLUTION FOR INTRAMUSCULAR INJECTION	HUMAN	3.0 ML IN A VIAL	3.0 ML IN A VIAL TYPE I NEUTRAL GLASS OF HYDROLYTIC CLASS 1, HERMETICALLY CLOSED WITH RUBBER PLUGS, AND CRIMPED OFF WITH ALUMINIUM AND PLASTIC TAMPER-PROOF CAPS.	6 MONTHS (UNOPENED VIAL) FOR BOTH COMPONENTS	JOINT STOCK COMPANY GENERIUM (JSC GENERIUM)	RUSSIA	FSBI N.F. GAMALEYA RCEM	N/A	31/03/2021
6	RWANDA FDA-AEU- 0006/2021	COVID-19 VACCINE JANSSEN	(AD26.COV2-S) RECOMBINANT	1.0 X 10 <sup>11</sup> VP/ML	SUSPENSION FOR INJECTION	HUMAN	VIAL CONTAINING 5 DOSES OF 0.5 ML	CARTON BOX CONTAINING 10 MULTIDOSE VIALS	3 MONTHS WHEN STORED AT 2°C – 8°C, 24 MONTHS WHEN STORED AT - 25 TO -150C	JOHNSON&JOHNSON COMPANY	USA	JANSSEN-CILAG INTERNATIONAL N.V.	N/A	11/06/2021
7	RWANDA FDA-AEU- 0007/2021	COVILO COVID-19 VACCINE (VERO CELL) INACTIVATED]	INACTIVATED SARS- COV-2 VIRUS ANTIGEN, ALUMINIUM HYDROXIDE ADJUVANT	3.9-10.4 UNITS, 0.3-0.6 MG/ML	SUSPENSION FOR INJECTION	HUMAN	DISABLE PRE-FILLED SYRINGE/VIAL OF 1.0 ML	DISABLE PRE-FILLED SYRINGE/VIAL	24 MONTHS.	BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO. LTD/ CHINA	CHINA	BEIJING INSTITUTE OF BIOLOGICAL PRODUCTS CO., LTD/ CHINA	N/A	17/07/2021



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### **RWANDA FDA AUTHORIZATION FOR EMERGENCY USE PRODUCTS-SEPTEMBER 2021**

8	RWANDA FDA-AEU- 0008/2021	CORONAVAC [COVID-19 VACCINE (VERO CELL) INACTIVATED]	INACTIVATED SARS-COV-2 VIRUS AS ANTIGEN	600SU	SUSPENSION FOR INJECTION	HUMAN	40 VIALS OF 0.5 ML PER BOX	VIAL	24 MONTHS	SINOVAC LIFE SCIENCES CO, LTD	CHINA	SINOVAC LIFE SCIENCES CO, LTD	N/A	17/07/2021
9	RWANDA FDA-AEU- 0009/2021	COVID-19 VACCINE MODERNA	COVID-19 MRNA VACCINE (NUCLEOSIDE MODIFIED)	EACH 0.5 ML DOSE OF COVID-19 VACCINE MODERNA CONTAINS 100 MICROGRAMS OF MESSENGER RNA (MRNA) (EMBEDDED IN SM-102 LIPID NANOPARTICLES)	DISPERSION FOR INJECTION	HUMAN	10 MULTIDOSE VIALS	TYPE I EQUIVALENT GLASS VIAL WITH A CHLOROBUTYL RUBBER STOPPER AND A FLIP-OFF PLASTIC CAP WITH SEAL (ALUMINIUM SEAL)	7 MONTHS	ROVI PHARMA INDUSTRIAL SERVICES, S.A.	SPAIN	MODERNA BIOTECH SPAIN, S.L	N/A	29/07/2021

**Dr. Emile BIENVENU**  
**Director General**

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