### 1.3.1.1 Approved professional information for INFLUVAC TETRA

**SCHEDULING STATUS:** S2

## 1. NAME OF THE MEDICINE

**INFLUVAC TETRA 2024**, suspension for injection in pre-filled syringe (influenza vaccine, surface antigen, inactivated).

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Influenza virus surface antigens (inactivated) (haemagglutinin and neuraminidase) of the following strains*:

| | |
|---|---|
| - A/Victoria/4897/2022 (H1N1)pdm09-like strain | |
| (A/Victoria/4897/2022, IVR-238) | 15 micrograms HA ** |
| - A/Thailand/8/2022 (H3N2)-like strain | |
| (A/Thailand/8/2022, IVR-237) | 15 micrograms HA ** |
| - B/Austria/1359417/2021-like strain | |
| (B/Austria/1359417/2021, BVR-26) | 15 micrograms HA ** |
| - B/Phuket/3073/2013-like strain | |
| (B/Phuket/3073/2013, wild type) | 15 micrograms HA ** |
| | per 0,5 mL dose |

* propagated in fertilised hens' eggs from healthy chicken flocks

** haemagglutinin.

Sugar free.

This vaccine complies with the World Health Organisation (WHO) recommendation (southern hemisphere) and EU recommendation for the 2024 season.

For a full list of excipients see section 6.1.

INFLUVAC TETRA may contain traces of eggs (such as ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin, which are used during the manufacturing process (see section 4.3).

## 3. PHARMACEUTICAL FORM

Suspension for injection in pre-filled syringe.

A colourless clear liquid, filled in single-dose syringes.

Free from visible particles.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Prophylaxis of influenza, especially those who run an increased risk of associated complications.

INFLUVAC TETRA is indicated in adults and children from 6 months of age.

The use of INFLUVAC TETRA should be based on official recommendations.

### 4.2 Posology and method of administration

**Posology**

Adults: 0,5 mL.

*Paediatric population*

Children from 6 months to 17 years of age: 0,5 mL.

Children younger than 9 years of age, who have not previously been vaccinated with a seasonal influenza vaccine: a second dose of 0,5 mL should be given after an interval of at least 4 weeks.

Infants younger than 6 months of age: the safety and efficacy of INFLUVAC TETRA have not been established.

**Method of administration**

Immunisation should be carried out by intramuscular or deep subcutaneous injection.

The preferred sites for intramuscular injection are the anterolateral aspect of the thigh (or the deltoid muscle if muscle mass is adequate) in children 6 months through 35 months of age, or the deltoid muscle in children from 36 months of age and adults.

Precautions to be taken before handling or administrating the medicinal product:

For instructions for preparation of the medicinal product before administration, see section 6.6.

### 4.3 Contraindications

Hypersensitivity to the active substances, to any of the excipients listed in section 6.1 or to any component that may be present as traces such as eggs (ovalbumin, chicken proteins), formaldehyde, cetyltrimethylammonium bromide, polysorbate 80 or gentamicin.

Immunisation shall be postponed in patients with febrile illness or acute infection.

### 4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicines, the name and the batch number of the administered product should be clearly recorded.

As with all injectable vaccines, appropriate medical treatment and supervision should always be readily available in case of an anaphylactic event following the administration of the vaccine.

INFLUVAC TETRA should under no circumstances be administered intravascularly.

As with other vaccines administered intramuscularly, INFLUVAC TETRA should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following an intramuscular administration to these patients.

Anxiety-related reactions, including vasovagal reactions (syncope), hyperventilation or stress-related reactions can occur following, or even before, any vaccination as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient

visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints.

INFLUVAC TETRA is not effective against all possible strains of influenza virus. INFLUVAC TETRA is intended to provide protection against those strains of virus from which the vaccine is prepared and to closely related strains.

As with any vaccine, a protective immune response may not be elicited in all vaccinees.

Antibody response in patients with endogenous or iatrogenic immunosuppression may be insufficient.

Interference with serological testing: see section 4.5.

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially sodium free.

This medicine contains potassium, less than 1 mmol (39 mg) per dose, i.e. essentially potassium free.

### 4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed. If INFLUVAC TETRA is given at the same time as other vaccines, immunisation should be carried out on separate limbs. It should be noted that the adverse reactions may be intensified.

The immunological response may be diminished if the patient is undergoing immunosuppressant treatment.

Following influenza vaccination, false-positive results in serology tests using the enzyme-linked immunosorbent assay (ELISA) method to detect antibodies against human immunodeficiency virus type 1 (HIV1), hepatitis C and especially human T-lymphotropic virus type 1 (HTLV1) have been observed. The western blot technique disproves the false-positive ELISA test results. The transient false-positive reactions could be due to the immunoglobulin M (IgM) response by the vaccine.

## 4.6 Fertility, pregnancy and lactation

### Pregnancy

Inactivated influenza vaccines can be used in all stages of pregnancy. Larger datasets on safety are available for the second and third trimester, compared with the first trimester; however, data from worldwide use of influenza vaccine do not indicate any adverse fetal and maternal outcomes attributable to the vaccine.

### Breastfeeding

INFLUVAC TETRA may be used during breastfeeding.

### Fertility

No fertility data are available.

## 4.7 Effects on ability to drive and use machines

INFLUVAC TETRA has no or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

*a. Summary of the safety profile*

The safety of INFLUVAC TETRA was assessed in three clinical trials. In two clinical trials healthy adults 18 years of age and older, and healthy children 3 to 17 years of age, were administered INFLUVAC TETRA or trivalent influenza vaccine Influvac. In a third study, the safety of INFLUVAC TETRA was assessed in healthy children from 6 months to 35 months of age administered INFLUVAC TETRA or a non-influenza vaccine control.

In both children studies, children from 6 months to 8 years of age received one or two doses of INFLUVAC TETRA depending on their influenza vaccination history.

Most reactions usually occurred within the first 3 days following vaccination and resolved spontaneously within 1 to 3 days after onset. The intensity of these reactions was generally mild.

In all age groups, the most frequently reported local adverse reaction after vaccination observed in the clinical studies for INFLUVAC TETRA was vaccination site pain.

The most frequently reported general adverse reactions after vaccination observed in the clinical studies for INFLUVAC TETRA in adults and children from 6 to 17 years of age were fatigue and headache, and for children from 3 to 5 years of age drowsiness, irritability and loss of appetite.

The most frequently reported general adverse reactions after vaccination observed in the clinical studies for INFLUVAC TETRA in children from 6 months to 35 months of age were irritability/fussiness.

Similar rates of solicited adverse reactions were observed in recipients of INFLUVAC TETRA and trivalent influenza vaccine Influvac.

The rates of solicited systemic adverse reactions were similar in recipients of INFLUVAC TETRA and the non-influenza vaccine, whereby the rates of solicited local adverse reactions were lower in recipients of INFLUVAC TETRA.

*b. Tabulated summary of adverse reactions*

The following undesirable effects are considered at least possibly related to INFLUVAC TETRA and have either been observed during the clinical trials with INFLUVAC TETRA or are resulting from post-marketing experience with INFLUVAC TETRA and/or the trivalent influenza vaccine Influvac.

The following frequencies apply:

Very common (≥ 1/10); common (≥ 1/100, < 1/10); uncommon (≥ 1/1 000, < 1/100); and not known (adverse reactions from post-marketing experience; cannot be estimated from the available data).

**Adults and elderly**

**Adverse reactions reported with INFLUVAC TETRA**

| **MedDRA System Organ Class** | **Very common ≥ 1/10** | **Common ≥ 1/100 to < 1/10** | **Uncommon ≥ 1/1 000 to < 1/100** | **Not known[a] (cannot be estimated from the available data)** |
|---|---|---|---|---|
| Blood and lymphatic system disorders | | | | Transient thrombocytopenia, transient lymphadenopathy |
| Immune system disorders | | | | Allergic reactions, in rare cases leading to shock, angioedema |
| Nervous system disorders | Headache[b] | | | Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré-syndrome |
| Vascular disorders | | | | Vasculitis associated in very rare cases with transient renal involvement |
| Skin and | | Sweating | | Generalised skin |

**Adverse reactions reported with INFLUVAC TETRA**

| **MedDRA System Organ Class** | **Very common ≥ 1/10** | **Common ≥ 1/100 to < 1/10** | **Uncommon ≥ 1/1 000 to < 1/100** | **Not known[a] (cannot be estimated from the available data)** |
|---|---|---|---|---|
| subcutaneous tissue disorders | | | | reactions including pruritus, urticaria or non-specific rash |
| Musculoskeletal and connective tissue disorders | | Myalgia, arthralgia | | |
| General disorders and administration site conditions | Fatigue<br>Local reaction: pain | Malaise, shivering<br>Local reactions: redness, swelling, ecchymosis, induration | Fever | |

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

[b] In elderly adults (≥ 61 years) reported as common.

**Paediatric population**

**Children (6 months to 17 years of age): Adverse reactions reported with INFLUVAC TETRA**

| **MedDRA System Organ Class** | **Very common ≥ 1/10** | **Common ≥ 1/100 to < 1/10** | **Uncommon ≥ 1/1 000 to < 1/100** | **Not known[a] (cannot be estimated from the available data)** |
|---|---|---|---|---|
| Blood and lymphatic system disorders | | | | Transient thrombocytopenia, transient lymphadenopathy |
| Immune system disorders | | | | Allergic reactions, in rare cases leading to shock, angioedema |
| Metabolism and nutrition disorders | Appetite loss[b] | | | |
| Psychiatric disorders | Irritability/fussiness[b] | | | |
| Nervous system disorders | Headache[c], drowsiness[b] | | | Neuralgia, paraesthesia, febrile convulsions, neurological disorders, such as encephalomyelitis, neuritis and Guillain Barré-syndrome |
| Vascular | | | | Vasculitis associated in |

**Children (6 months to 17 years of age): Adverse reactions reported with INFLUVAC TETRA**

| **MedDRA System Organ Class** | **Very common ≥ 1/10** | **Common ≥ 1/100 to < 1/10** | **Uncommon ≥ 1/1 000 to < 1/100** | **Not known[a] (cannot be estimated from the available data)** |
|---|---|---|---|---|
| disorders | | | | very rare cases with transient renal involvement |
| Gastrointestinal disorders | Nausea[c], abdominal pain[c], diarrhoea[e], vomiting[e] | | | |
| Skin and subcutaneous tissue disorders | Sweating[f] | | | Generalised skin reactions including pruritus, urticaria or non-specific rash |
| Musculoskeletal and connective tissue disorders | Myalgia[c] | Arthralgia[c] | | |
| General disorders and administration site conditions | Fatigue[c], fever[f], malaise[c] Local reactions: pain, redness, swelling[d], induration[d] | Shivering[c] Local reaction: ecchymosis | | |

[a] Because these reactions are reported voluntarily from a population of uncertain size, it is not

d

**Children (6 months to 17 years of age): Adverse reactions reported with INFLUVAC TETRA**

| MedDRA System Organ Class | Very common ≥ 1/10 | Common ≥ 1/100 to < 1/10 | Uncommon ≥ 1/1 000 to < 1/100 | Not known[a] (cannot be estimated from the available data) |
|---|---|---|---|---|

possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

[b] Reported in children 6 months to 5 years of age.

[c] Reported in children 6 to 17 years of age.

[d] Reported as common in children 6 to 35 months of age.

[e] Reported as common in children 3 to 5 years of age.

[f] Reported as common in children 3 to 17 years of age.

*Reporting of suspected adverse reactions*

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Health care professionals are asked to report any suspected adverse reactions to SAHPRA via the **6.04 Adverse Drug Reactions Reporting Form**, found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8.

### 4.9 Overdose

Overdosage is unlikely to have any untoward effect.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Influenza vaccine, ATC Code: J07BB02.

**Mechanism of action**

INFLUVAC TETRA provides active immunisation against four influenza virus strains: an A/(H1N1) strain, an A/(H3N2) strain, and two B strains (one from each lineage; B/(Victoria) and B/(Yamagata)). INFLUVAC TETRA, manufactured according to the same process as trivalent influenza vaccine Influvac, induces humoral antibodies against the haemagglutinins. These antibodies neutralise influenza viruses.

Specific levels of haemagglutination-inhibition (HI) antibody titre post-vaccination with inactivated influenza virus vaccines have not been correlated with protection from influenza illness but the HI antibody titres have been used as a measure of vaccine activity.

An immune response is generally obtained within 2 to 3 weeks. The duration of post vaccinal immunity to homologous strains or to strains closely related to the vaccine strains varies but is usually 6 – 12 months.

**Pharmacodynamic effects**

*Efficacy of INFLUVAC TETRA in children 6 – 35 months of age:*

The efficacy of INFLUVAC TETRA was evaluated in a randomised, observer-blind, non-influenza vaccine-controlled study (INFQ3003) conducted during 3 influenza seasons 2017 to 2019 in Europe and Asia. Healthy subjects aged 6 – 35 months received two doses of INFLUVAC TETRA (N = 1 005) or non-influenza control vaccine (N = 995) approximately 28 days apart. The efficacy of INFLUVAC TETRA was assessed for the prevention of reverse transcription polymerase chain reaction (RT-PCR) – confirmed influenza A and/or B disease due to any influenza strain. All RT-PCR-positive specimens were further tested for viability in cell culture and to determine whether the circulating viral strains matched those in the vaccine.

**Table: Efficacy in children 6 – 35 months of age**

| **Adults 18 – 60 years of age** | INFLUVAC TETRA N = 1 005 | Non-influenza control vaccine N = 995 | Vaccine efficacy (95 % CI) |
|---|---|---|---|
| **Laboratory-** | N | N | |

| | | | |
|---|---|---|---|
| **confirmed influenza caused by:** | | | |
| – **Any influenza A or B strain** | 59 | 117 | 0,54 (0,37 – 0,66) |
| – **Culture confirmed vaccine matching strains** | 19 | 56 | 0,68 (0,45 – 0,81) |

Vaccine efficacy: proportion of influenza cases prevented by the vaccination.

N = number of subjects vaccinated.

n = number of influenza cases.

CI = confidence interval.

*Immunogenicity of INFLUVAC TETRA compared to trivalent Influvac:*

Clinical studies performed in adults of 18 years of age and older (INFQ3001) and children of 3 to 17 years of age (INFQ3002) assessed the safety and immunogenicity of INFLUVAC TETRA and its non-inferiority to trivalent influenza vaccine Influvac for the post-vaccination HI geometric mean antibody titre (GMT).

In both studies the immune response elicited by INFLUVAC TETRA against the three strains in common was non-inferior to trivalent influenza vaccine Influvac. INFLUVAC TETRA elicited a superior immune response against the additional B strain included in INFLUVAC TETRA compared to trivalent influenza vaccine Influvac.

*Adults 18 years of age and older:*

In clinical study INFQ3001, 1 535 adults of 18 years of age and older received a single dose of

INFLUVAC TETRA and 442 subjects received a single dose of trivalent Influvac:

**Table: Post-vaccination GMT and seroconversion rates**

| **Adults 18 – 60 years of age** | INFLUVAC TETRA N = 768 | Influvac[1] N = 112 | Influvac[2] N = 110 |
|---|---|---|---|
| | **GMT (95 % confidence interval)** | | |
| **A/H1N1** | 272,2 (248,0; 298,8) | 304,4 (235,1; 394,1) | 316,0 (245,1; 407,3) |
| **A/H3N2** | 442,4 (407,6; 480,2) | 536,5 (421,7; 682,6) | 417,0 (323,7; 537,1) |
| **B (Yamagata)[3]** | 162,5 (147,8; 178,7) | 128,7 (100,3; 165,2) | 81,7 (60,7; 109,9) |
| **B (Victoria)[4]** | 214,0 (195,5; 234,3) | 85,1 (62,6; 115,6) | 184,7 (139,0; 245,3) |
| | **Seroconversion rates (95 % confidence interval)** | | |
| **A/H1N1** | 59,4 % (55,8 %; 62,9 %) | 65,5 % (55,8 %; 74,3 %) | 64,8% (55,0 %; 73,8 %) |
| **A/H3N2** | 51,3 % (47,7 %; 54,9 %) | 61,6 % (51,9 %; 70,6 %) | 55,5 % (45,7 %; 64,9 %) |
| **B (Yamagata)[3]** | 59,2 % (55,7 %; 62,8 %) | 58,7 % (48,9 %; 68,1 %) | 40,9 % (31,6 %; 50,7 %) |
| **B (Victoria)[4]** | 70,2 % (66,8 %; 73,4 %) | 51,4 % (41,6 %; 61,1 %) | 66,4 % (56,7 %; 75,1 %) |

| **Elderly 61 years of age and older** | INFLUVAC TETRA N = 765 | Influvac[1] N = 108 | Influvac[2] N = 110 |
|---|---|---|---|
| | **GMT (95 % confidence interval)** | | |
| **A/H1N1** | 127,2 (114,9; 140,9) | 142,4 (107,6; 188,3) | 174,2 (135,9; 223,3) |
| **A/H3N2** | 348,5 (316,8; 383,5) | 361,5 (278,3; 469,6) | 353,4 (280,7; 445,0) |
| **B (Yamagata)[3]** | 63,7 (57,7; 70,4) | 57,4 (43,6; 75,7) | 27,3 (20,7; 36,0) |
| **B (Victoria)[4]** | 109,4 (98,1; 122,0) | 48,0 (34,6; 66,6) | 106,6 (79,7; 142,8) |

| | **Seroconversion rates (95 % confidence interval)** | | |
|---|---|---|---|
| **A/H1N1** | 50,3 % (46,7 %; 54,0 %) | 56,6 % (46,6 %; 66,2 %) | 58,2 % (48,4 %; 67,5 %) |
| **A/H3N2** | 39,3 % (35,8 %; 42,9 %) | 44,4 % (34,9 %; 54,3 %) | 43,6 % (34,2 %; 53,4 %) |
| **B (Yamagata)[3]** | 49,9 % (46,2 %; 53,5 %) | 46,2 % (36,5 %; 56,2 %) | 30,0 % (21,6 %; 39,5 %) |
| **B (Victoria)[4]** | 53,6 % (50,0 %; 57,2 %) | 25,0 % (17,2 %; 34,3 %) | 55,6 % (45,7 %; 65,1 %) |

N = number of subjects included in efficacy analysis.

[1] Containing A/H1N1, A/H3N2 and B (Yamagata lineage).

[2] Containing A/H1N1, A/H3N2 and B (Victoria lineage).

[3] Recommended B strain by WHO for the season 2014 – 2015 NH for trivalent vaccines.

[4] Additional recommended B strain by WHO for season 2014 – 2015 NH for quadrivalent vaccines.

***Paediatric population***

*Children 3 – 17 years of age:*

In clinical study INFQ3002, 402 children of 3 to 17 years of age received one or two doses of INFLUVAC TETRA and 798 children received one or two doses of trivalent Influvac based on their influenza vaccination history.

**Table: Seroconversion rates**

| **Children 3 – 17 years of age** | INFLUVAC TETRA N = 396 | Influvac[1] N = 389 | Influvac[2] N = 399 |
|---|---|---|---|
| | **Seroconversion rates (95 % confidence interval)** | | |

| | | | |
|---|---|---|---|
| **A/H1N1** | 60,1 % (55,1 %; 65,0 %) | 61,8 % (56,7 %; 66,6 %) | 59,1 % (54,1 %; 64,0 %) |
| **A/H3N2** | 80,6 % (76,3 %; 84,3 %) | 82,4 % (78,3 %; 86,1 %) | 80,7 % (76,5 %; 84,5 %) |
| **B (Yamagata)[3]** | 79,3 % (75,0 %; 83,2 %) | 73,1 % (68,4 %; 77,5 %) | 28,1 % (23,7 %; 32,8 %) |
| **B (Victoria)[4]** | 76,5 % (72,0 %; 80,6 %) | 39,5 % (34,6 %; 44,6 %) | 72,7 % (68,0 %; 77,0 %) |

N = number of subjects included in immunogenicity analysis.

[1] Containing A/H1N1, A/H3N2 and B (Yamagata lineage).

[2] Containing A/H1N1, A/H3N2 and B (Victoria lineage).

[3] Recommended B strain by WHO for the season 2016-2017 NH for trivalent vaccines.

[4] Additional recommended B strain by WHO for season 2016-2017 NH for quadrivalent vaccines.

*Children 6 months – 35 months of age:*

In clinical study INFQ3003, the immunogenicity of INFLUVAC TETRA was evaluated in terms of seroconversion rates across 3 influenza seasons.

**Table: Seroconversion rates**

| **Children 6 – 35 months of age** | Influenza season NH 2017 – 2018[1] N = 348 | Influenza season NH 2018 – 2019[1] N = 359 | Influenza season SH 2019[1] N = 225 |
|---|---|---|---|
| | **Seroconversion rates (95 % confidence interval)** | | |
| **A/H1N1** | 74,4 % (69,5 %; 78,9 %) | 76,0 % (71,3 %; 80,4 %) | 69,8 % (63,3 %; 75,7 %) |
| **A/H3N2** | 92,5 % (89,2 %; 95,0 %) | 86,6 % (82,7 %; 90,0 %) | 86,2 % (81,0 %; 90,4 %) |
| **B (Yamagata)** | 35,5 % (30,4 %; 40,8 %) | 56,0 % (50,7 %; 61,2 %) | 16,9 % (12,2 %; 22,4 %) |
| **B (Victoria)** | 26,5 % (21,9 %; 31,5 %) | 65,2 % (60,0 %; 70,1 %) | 47,6 % (40,9 %; 54,3 %) |

N = number of subjects included in immunogenicity analysis.

[1] Containing recommended strains by WHO for respective season for quadrivalent vaccines.

The European Medicines Agency has deferred the obligation to submit the results of studies with INFLUVAC TETRA in one or more subsets of the paediatric population.

### 5.2 Pharmacokinetic properties

Not applicable.

### 5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of repeat dose and local toxicity, reproductive and developmental toxicity and safety pharmacology studies.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Calcium chloride dihydrate

Disodium phosphate dihydrate

Magnesium chloride hexahydrate

Potassium chloride

Potassium dihydrogen phosphate

Sodium chloride

Water for injections.

### 6.2 Incompatibilities

In the absence of compatibility studies, INFLUVAC TETRA must not be mixed with other medicinal products.

### 6.3 Shelf life

1 year.

### 6.4 Special precautions for storage

Store in a refrigerator (2 °C – 8 °C). Do not freeze.

Store in the original package in order to protect from light.

### 6.5 Nature and contents of container

0,5 mL suspension for injection in pre-filled syringe with or without needle (clear glass, type I). The glass syringe is closed at one end with a rubber plunger and at the other end with a rubber tip cap. The plunger consists of a grey coloured bromobutyl rubber compound. The plunger rod consists of polypropylene and is screwed into the rubber plunger. Each syringe can only be used once.

Pack of 1 or 10.

Not all pack sizes may be marketed.

### 6.6 Special precautions for disposal and other handling

The vaccine should be allowed to reach room temperature before use.

Shake before use. Inspect visually prior to administration.

Any unused product or waste material should be disposed of in accordance with local requirements.

## 7. HOLDER OF CERTIFICATE OF REGISTRATION

Abbott Laboratories S.A. (Pty) Ltd

Abbott Place, 219 Golf Club Terrace

Constantia Kloof 1709

South Africa

## 8. REGISTRATION NUMBER

52/30.1/0094

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

11 August 2020

## 10. DATE OF REVISION OF THIS TEXT

5 February 2024

## NAME AND ADDRESS OF MANUFACTURER

Abbott Biologicals B.V.

Veerweg 12,

8121 AA, Olst

The Netherlands