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Tel.: (0832) 6624502 / 6682000, Fax: (0832) 6680156.

E-mail: zephyr@tulipgroup.com**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 1 of 8

Section 1: Identification of the substance /mixture and of the company undertaking**1.1 Product identifier****Product name:** FIAcheck™ PSA Device**Product code:** 536010010**1.2 Relevant identified uses of the substance or mixture and uses advised against****Use of substance/mixture:** Fluorescence Immunoassay intended for Quantitative determination of Prostate Specific Antigen in human Serum and Plasma. This reagent is intended for IN VITRO diagnostic use only. NOT FOR USE IN HUMANS.**1.3 Details of the supplier of the safety data sheet****Company name:** Zephyr Biomedicals,
A Division of Tulip Diagnostics (P) Ltd.
Plot nos. M 46-47, Phase III B,
Verna Industrial Estate,
Verna, Goa - 403 722,
INDIA.
www.tulipgroup.com**Tel:** +91 (0832) 6682000 / 6624502**Fax:** (0832) 6680156**Email:** zephyr@tulipgroup.com**1.4 Emergency telephone number****Emergency tel:** +91 (0832) 6682000 / +91 (0832) 6624502
(office hours only)

Issue No. 02

Issue date: 08-12-2023

Sign/Date:

(QC Dept.)

**Zephyr Biomedicals**
A Division of Tulip Diagnostics (P) Ltd.**Corporate Office:** Gilanjali, Tulip Block, Dr. Antonio Do Rego Bagh, Bambolim Complex
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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 2 of 8

Section 2 : Hazards identification**2.1 Classification of the substance or mixture**

Classification under CLP: This product has no classification under CLP.

The product is regulated as an in vitro diagnostic medical device and is not considered hazardous in accordance with regulation (EC) No.1272/2008.

2.2 Label elements

Label elements: None are present.

Precautionary statements: P102: Keep out of reach of children.

P234: Keep only in original container.

2.3 Other hazards

PBT: This product is not identified as a PBT/vPvB substance.

Section 3 : Composition /information on ingredients**3.1 Substances**

Chemical identity: In-vitro Diagnostic test for determination of Prostate Specific Antigen in human Serum and Plasma.

Contains: Contains no hazardous substances in reportable quantities under the CLP.

Section 4 : First aid measures**4.1 Description of first aid measures**

Skin contact: Wash immediately with plenty of soap and water

Eye contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so.
Continue rinsing. If eye irritation persists, seek medical advice/attention.

Ingestion: Do not induce vomiting. Wash mouth with water and give plenty of water to drink immediately. Obtain medical attention if necessary and show label on container.

Inhalation: Irritation is unlikely to occur but in the event of discomfort, provide plenty of fresh air and if necessary seek medical assistance.

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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 3 of 8

4.2 Most important symptoms and effects, both acute and delayed

Skin contact: There may be mild irritation at the site of contact.
Eye contact: There may be irritation and redness.
Ingestion: There may be irritation of the throat.
Inhalation: No symptoms.

4.3 Indication of any immediate medical attention and special treatment needed

Immediate / special treatment: Not applicable.

Section 5: Fire -fighting measures**5.1 Extinguishing media**

Extinguishing media: Suitable extinguishing media such as carbon dioxide, dry chemical powder or polymer foam for the surrounding fire should be used.
Use water spray to cool containers.

5.2 Special hazards arising from the substance or mixture

Exposure hazards: No known specific hazards

5.3 Advice for fire fighters

Advice for fire-fighters: Do not enter fire without proper protective equipment, including respiratory protection.

Section 6: Accidental release measures**6.1 Personal precautions, protective equipment and emergency procedures**

1. Follow Standard Biosafety guidelines during handling of potentially infectious human specimens.
2. Refer to section 8 of SDS for personal protection details.
3. Turn leaking containers leak-side up prevent the escape of liquid.

6.2 Environmental precautions

Environmental precautions: Do not discharge into drains or rivers.

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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 4 of 8

6.3 Methods and material for containment and cleaning up

Clean-up procedures: For small spills, clean up with paper/cloth, or mop up, and dispose off safely.
Clean area of spillage down with plenty of water.

6.4 Reference to other sections

Reference to other sections: Refer to section 8 of SDS.

Section 7: Handling and storage**7.1 Precautions for safe handling**

Handling requirements: Refer IFU for FIAcheck™ PSA Device.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions: Store in original container between 4°C to 30°C.

Suitable packaging: Must only be kept in original packaging.

7.3 Specific end use(s)

Specific end use(s): Refer Section 1.2

Section 8: Exposure controls/personal protection**8.1 Control parameters**

Workplace exposure limits: Contains no substance with occupational exposure limit values.

DNEL/PNEC Values

DNEL / PNEC: No data available.

8.2 Exposure controls

Engineering measures: Ensure all engineering measures mentioned in section 7 of SDS are in place.

Respiratory protection: Respiratory protection not required. Ensure adequate ventilation.

Hand protection: Disposable gloves.

Eye protection: No specific measures are required when using good safe practice.

Skin protection: Protective clothing not required in normal use. Use proper glove removal technique to avoid skin contact.

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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 5 of 8

Section 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties**

	Device
State :	Solid
Colour :	White
Odour :	Odourless
Solubility in water :	Insoluble
Viscosity :	Not Applicable
Boiling point/range°C:	No data available
Flash point°C:	No data available
Vapour pressure:	No data available
Melting point/range°C:	No data available
Auto flammability°C:	No data available
Relative density:	No data available

9.2 Other Information

Other information: No data available.

Section 10: Stability and reactivity**10.1 Reactivity**

Reactivity: Stable under recommended transport or storage conditions.

10.2 Chemical stability

Chemical stability: Stable under normal conditions.

10.3 Possibility of hazardous reactions

Hazardous reactions: Hazardous reactions will not occur under normal transport or storage conditions.

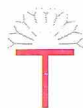
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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 6 of 8

10.4 Conditions to avoid**Conditions to avoid:** Heat and moisture**10.5 Incompatible materials****Materials to avoid:** Strong acids /alkalines, oxidising / reducing agents.**10.6 Hazardous decomposition products****Hazardous decomposition products:** No known hazardous decomposition products are formed in high quantities.**Section 11: Toxicological information****Section 11.1 Information on Toxicological effects****Toxicity values:** No data available.**Symptoms/routes of exposure****Skin contact:** There may be mild irritation at the site of contact**Eye contact:** There may be irritation and redness.**Ingestion:** There may be irritation of the throat.**Inhalation:** No symptoms.**Section 12: Ecological information****12.1 Toxicity****Ecotoxicity values:** No data available.**12.2 Persistence and degradability****Persistence and degradability:** No data available.**12.3 Bioaccumulative potential****Bioaccumulative potential:** No data available.**12.4 Mobility in soil****Mobility:** No data available.

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**SAFETY DATA SHEET
FIAcheck™ PSA Device**

Page 7 of 8

12.5 Results of PBT and vPvB assessment**PBT identification:** This product is not identified as a PBT/vPvB substance.**12.6 Other adverse effects****Other adverse effects:** Negligible ecotoxicity.**Section 13: Disposal considerations****13.1 Waste treatment methods****Disposal operations:** Dispose off in accordance with current legislation and local authority regulations as per established safety procedures.**NB:** The user's attention is drawn to the possible existence of regional or national regulations regarding disposal.**Section 14: Transport information****14.1 UN number****UN number:** N/A**14.2 UN proper shipping name****Shipping name:** This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID).**14.3 Transport hazard class(es)**

Non -hazardous for transport.

14.4 Packing group

N/A

14.5 Environmental hazards**Environmentally hazardous :** No**Marine pollutant:** No

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**SAFETY DATA SHEET
FIACheck™ PSA Device**

Page 8 of 8

14.6 Special precautions for user**Special precautions:**

1. Shipper boxes should be arranged / stacked in the direction as indicated the shipper label/ Carton.
2. Avoid over-stacking. Do not stack more than 5 boxes.

Section 15: Regulatory information**15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture****Specific regulations:** Applicable national / regional or local regulations.

Safe for all kinds of modes of transportation.

15.2 Chemical Safety assessment

Not carried out for this product.

Section 16: Other information**Other information:** This safety data sheet is prepared in accordance with Commission Regulation (EU) No 453/2010.**Legal disclaimer:** The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. This company shall not be held liable for any damage resulting from handling or from contact with the above product.

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