CERTIFICED MEDICAL DEVICE

**{{DeviceName}}**

|  |  |  |
| --- | --- | --- |
| **Report N:** COA/FP/{{BatchNo}} | | **Certification Date:** {{COAdate}} |
| **Lot N:** {{LotNo}} | **MFG Date:** {{MFGdate}} | **EXP Date:** {{EXPdate}} |
| **Lot Size:** {{LotSize}} | **Sample Size:** {{SampleSize}} | **Ref N:** {{ProductCode}} |

**Description:** {{Description}}.

**Instruction for use:** {{IFU}}.

**Parameters considered for analysis of {{DeviceName}}:**

|  |  |  |  |
| --- | --- | --- | --- |
| S. N. | Testing parameter for analysis | Acceptance criteria | Mode of inspection |
|  | {{parameter1}} | {{criteria1}} | {{inspectionMode1}} |
|  | {{parameter2}} | {{criteria2}} | {{inspectionMode2}} |
|  | {{parameter3}} | {{criteria3}} | {{inspectionMode3}} |
|  | {{parameter4}} | {{criteria4}} | {{inspectionMode4}} |
|  | {{parameter5}} | {{criteria5}} | {{inspectionMode5}} |
|  | {{parameter6}} | {{criteria6}} | {{inspectionMode6}} |
|  | {{parameter7}} | {{criteria7}} | {{inspectionMode7}} |
|  | {{parameter8}} | {{criteria8}} | {{inspectionMode8}} |
|  | {{parameter9}} | {{criteria9}} | {{inspectionMode9}} |
|  | {{parameter10}} | {{criteria10}} | {{inspectionMode10}} |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analysis | {{parameter1}} | {{parameter2}} | {{parameter3}} | {{parameter4}} | {{parameter5}} | {{parameter6}} | {{parameter7}} | {{parameter8}} | {{parameter9}} | {{parameter10}} |
|  |  |  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Average |  |  |  |  |  |  |  |  |  |  |
| Std Dev |  |  |  |  |  |  |  |  |  |  |
| Certified |  |  |  |  |  |  |  |  |  |  |

C: Complies with the acceptance criteria, NC: Not complies with the acceptance criteria

**Certification Process:** Analysis of product conformity is conducted in accordance to the standard operating procedure defined by the Company. All the procedures are in accordance to the international standards and validated.

**Analysis:** {{DeviceName}} complies with the inhouse specification. {{DeviceName}} has passed the above-mentioned inspection tests.

**Expiration of Certification:** This certificate of {{DeviceName}} with {{ProductCode}}. {{BatchNo}} is valid for {{EXPmonth}} months after the purchase date.

**Description:** {{Description}}.

**Instruction for use:** {{IFU}}.

**Labeling Requirements:** Companies {{DeviceName}} complies with the labeling requirements of ISO 15223-1:2021, EN 1041: 2008+A1:2013 and Labeling requirements of {{DestinationCountry}}.

**Storage conditions:** {{StorageCondition}}.

**Reference standards:** {{ISO}}

{{sign}}

**Verified By:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date: {{COAdate}}

{{InspectedBy}}

Analytical chemist

(in-charge Quality Control)