CERTIFICED MEDICAL DEVICE

**BP Monitor**

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| --- | --- | --- |
| **Report N:** COA/FP/542 | | **Certification Date:** 25-08-2022 |
| **Lot N:** 542 | **MFG Date:** 08-22 | **EXP Date:** 8-27 |
| **Lot Size:** 54 | **Sample Size:** 51 | **Ref N:** T12 |

**Description:** BP monitor is a electronic medical device which is used to measure the Blood Pressure of a patient.

**Instruction for use:** As per the insctruction given .

**Parameters considered for analysis of BP Monitor:**

|  |  |  |  |
| --- | --- | --- | --- |
| S. N. | Testing parameter for analysis | Acceptance criteria | Mode of inspection |
|  | Thickness | 10.0±0.12 | Vernier caliper |
|  | Width | 5.0±0.12 | Vernier caliper |
|  | Length | 30.0±1.11 | Vernier caliper |
|  | Hole size | 2.0+0.16 | Vernier caliper |
|  | Shape | Similar | Visual |
|  | Thickness | Similar | Vernier caliper |
|  | Width | Similar | Vernier caliper |
|  | Length | Similar | Vernier caliper |
|  | Hole size | Similar | Vernier caliper |
|  | Shape | Similar | Visual |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Analysis | Thickness | Width | Length | Hole size | Shape | Thickness | Width | Length | Hole size | Shape |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 9.95 | 5.03 | 30.03 | 2.1 | C | C | C | C | C | C |
| 2 | 10.04 | 4.96 | 30.53 | 2.08 | C | C | C | C | C | C |
| 3 | 10.11 | 4.95 | 29.77 | 2.13 | C | C | C | C | C | C |
| 4 | 10.01 | 5.06 | 29.16 | 2.06 | C | C | C | C | C | C |
| 5 | 9.97 | 5.08 | 30.27 | 2.09 | C | C | C | C | C | C |
| 6 | 10.01 | 5.08 | 29.05 | 2.0 | C | C | C | C | C | C |
| 7 | 9.95 | 4.94 | 30.92 | 2.11 | C | C | C | C | C | C |
| 8 | 9.89 | 5.05 | 30.01 | 2.09 | C | C | C | C | C | C |
| 9 | 9.9 | 5.09 | 30.07 | 2.08 | C | C | C | C | C | C |
| 10 | 9.94 | 4.99 | 30.28 | 2.09 | C | C | C | C | C | C |
| 11 | 10.08 | 4.97 | 30.91 | 2.12 | C | C | C | C | C | C |
| 12 | 10.09 | 5.07 | 30.08 | 2.14 | C | C | C | C | C | C |
| 13 | 10.03 | 5.06 | 29.89 | 2.1 | C | C | C | C | C | C |
| 14 | 10.04 | 4.96 | 30.13 | 2.13 | C | C | C | C | C | C |
| 15 | 10.0 | 4.91 | 30.61 | 2.07 | C | C | C | C | C | C |
| 16 | 10.11 | 4.94 | 29.54 | 2.15 | C | C | C | C | C | C |
| 17 | 9.96 | 5.08 | 29.82 | 2.11 | C | C | C | C | C | C |
| 18 | 10.01 | 4.94 | 29.03 | 2.02 | C | C | C | C | C | C |
| 19 | 9.92 | 5.09 | 29.58 | 2.16 | C | C | C | C | C | C |
| 20 | 9.89 | 5.06 | 29.8 | 2.13 | C | C | C | C | C | C |
| 21 | 10.05 | 4.91 | 30.24 | 2.15 | C | C | C | C | C | C |
| 22 | 10.12 | 5.11 | 31.09 | 2.11 | C | C | C | C | C | C |
| 23 | 10.01 | 4.9 | 31.05 | 2.0 | C | C | C | C | C | C |
| 24 | 10.0 | 4.93 | 30.08 | 2.04 | C | C | C | C | C | C |
| 25 | 10.06 | 5.07 | 31.1 | 2.11 | C | C | C | C | C | C |
| 26 | 10.05 | 4.98 | 30.56 | 2.01 | C | C | C | C | C | C |
| 27 | 10.05 | 4.97 | 29.9 | 2.04 | C | C | C | C | C | C |
| 28 | 10.04 | 4.88 | 28.94 | 2.1 | C | C | C | C | C | C |
| 29 | 9.99 | 5.03 | 31.05 | 2.11 | C | C | C | C | C | C |
| 30 | 10.11 | 4.94 | 30.79 | 2.13 | C | C | C | C | C | C |
| 31 | 10.06 | 5.1 | 29.72 | 2.12 | C | C | C | C | C | C |
| 32 | 9.92 | 5.03 | 30.54 | 2.01 | C | C | C | C | C | C |
| 33 | 9.95 | 4.91 | 30.0 | 2.01 | C | C | C | C | C | C |
| 34 | 9.99 | 4.99 | 29.34 | 2.11 | C | C | C | C | C | C |
| 35 | 9.99 | 4.94 | 30.13 | 2.15 | C | C | C | C | C | C |
| 36 | 9.97 | 5.09 | 30.64 | 2.11 | C | C | C | C | C | C |
| 37 | 10.09 | 5.06 | 29.56 | 2.13 | C | C | C | C | C | C |
| 38 | 9.98 | 5.07 | 30.15 | 2.09 | C | C | C | C | C | C |
| 39 | 9.88 | 4.93 | 29.37 | 2.01 | C | C | C | C | C | C |
| 40 | 10.12 | 5.01 | 29.33 | 2.1 | C | C | C | C | C | C |
| 41 | 9.98 | 4.89 | 30.69 | 2.04 | C | C | C | C | C | C |
| 42 | 10.01 | 4.98 | 30.11 | 2.02 | C | C | C | C | C | C |
| 43 | 10.08 | 5.03 | 30.91 | 2.15 | C | C | C | C | C | C |
| 44 | 10.0 | 5.04 | 30.97 | 2.13 | C | C | C | C | C | C |
| 45 | 10.08 | 4.94 | 30.16 | 2.13 | C | C | C | C | C | C |
| 46 | 9.99 | 4.99 | 29.04 | 2.01 | C | C | C | C | C | C |
| 47 | 10.05 | 4.98 | 29.26 | 2.06 | C | C | C | C | C | C |
| 48 | 9.97 | 4.9 | 29.51 | 2.06 | C | C | C | C | C | C |
| 49 | 9.94 | 5.01 | 29.24 | 2.15 | C | C | C | C | C | C |
| 50 | 10.11 | 4.91 | 30.63 | 2.07 | C | C | C | C | C | C |
| 51 | 10.08 | 5.05 | 29.34 | 2.09 | C | C | C | C | C | C |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Average | 10.01 | 5.0 | 30.06 | 2.09 | C | C | C | C | C | C |
| Std Dev | 0.02 | 1.683 | 6.587 | 2.65 |  |  |  |  |  |  |
| Certified | 10.01 | 5.0 | 30.06 | 2.09 | C | C | C | C | C | C |

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:** BP Monitor complies with the inhouse specification. BP Monitor has passed the above-mentioned inspection tests.

**Expiration of Certification:** This certificate of BP Monitor with T12. 542 is valid for months after the purchase date.

**Description:** BP monitor is a electronic medical device which is used to measure the Blood Pressure of a patient.

**Instruction for use:** As per the insctruction given .

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

**Storage conditions:** .

**Reference standards:** ISO 13484



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

Date: 25-08-2022

Arun

Analytical chemist

(in-charge Quality Control)