MCAZ Medicines Control Authority of Zimbabwe

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**REF:** B/279/29/26/2018

16 March 2018

Att: Boney Moolayil
**Beta Healthcare Products (Pvt) Ltd**
**Plot No. 2.21B, Cochin Special Economic Zone, Kakkanad, Kochi, Kerala state, India.**

Dear Sir

**RE: QUALITY AUDIT OF GLOVE MANUFACTURING PREMISES**

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|---|---|
| **NAME OF MANUFACTURER:** | **Beta Healthcare Products (Pvt) Ltd** |
| **MANUFACTURING SITE ADDRESS:** | **Plot No. 2.21B, Cochin Special Economic Zone, Kakkanad, Kochi, Kerala state, India.** |
| **TYPE OF PRODUCTS:** | **Medical Gloves** |
| **DATE OF AUDIT:** | **30 and 31 August 2017** |
| **PROPOSED DATE OF NEXT AUDIT:** | **September 2020** |

We refer to the inspection of **Beta Healthcare** glove manufacturing plant to verify compliance with international standards for the manufacture of Medical Devices.

The inspection report was tabled at the 151st meeting of the MCAZ Laboratory Committee held on the 21st of November 2017. This letter serves to inform you that based on the findings from the inspection and satisfactory submission and verification of corrective actions; **Beta Healthcare Products (Pvt) Ltd** was found to be operating in compliance with ISO 13485: Medical Devices-Quality Management Systems-Requirement for Regulatory Purposes for the **manufacture of medical gloves only**.

Please be advised that the facility will be due for another audit three years from the date of the current audit.

**MEDICINES CONTROL AUTHORITY OF ZIMBABWE**

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G. N. MAHLANGU (Ms)
**DIRECTOR GENERAL**

MCAZ Medicines Control Authority of Zimbabwe

**MEDICAL DEVICES LAB**

**Review of corrective actions for BetaHealthcare Glove Manufacturing Factory 2017**

| Non Conformance | CAPA Submitted from Factory – BetaHealthcare | Auditor's Comments |
|---|---|---|
| At the time of audit, there was no separation of incoming raw materials and QC checked/passed raw materials by way of space demarcations to avoid mix-up. Only stickers/labels were used.<br><br>**NC #1** | (i) The quarantine area for incoming raw materials arranged. Photo graph attached.<br>(ii) The separate area was allocated for approved raw materials with proper separation to avoid mix-up. Photograph attached. | NC cleared pending on-site verification in the next scheduled audit. |
| At the time of audit, some equipment items were not uniquely identified or labeled e.g. digital analytical balance and digital weighing balance in the production area.<br><br>**NC #2** | (i) The list of equipment was revised, which included equipment identification number. The ID no. was provided on the equipment. Photograph attached. The revised equipment list is attached. (ii) Training was imparted to lab chemist. Training record is attached. | Submitted objective evidence for the corrective action adequate and satisfactory.<br><br>NC cleared. |
| At the time of audit, there were no directions or signs for location of emergency exit areas, emergency assembly points and fire extinguisher points in case of fire outbreak.<br><br>**NC #3** | The sign boards of directions, emergency exit, fire extinguisher and evacuation plan are displayed in entire production area. The photograph attached. The training is imparted to maintenance engineer regarding safety and the training record is attached. | NC cleared pending on-site verification in the next scheduled audit. |
| At the time of audit, there was no signature master list to verify signatories for critical documents and reports<br><br>**NC #4** | The signature master list prepared with effect from 02.02.2018. Copy is attached. | Submitted objective evidence for the corrective action adequate and satisfactory.<br><br>NC cleared. |

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| At the time of audit, there were no labels for easy identification in the packaging material warehouse.<br><br>**NC #5** | All packing materials are identified. The photograph is attached. | NC cleared pending on-site verification in the next scheduled audit. |

**Recommendations:**

(i) Submitted corrective actions for NC 1, NC 3 and NC 5 to be verified on site in the next scheduled Factory Audit.

(ii) Approving the factory (**BetaHealthcare, India**) to manufacture gloves for the Zimbabwean market.

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| **Prepared by:** | AM | **Date:** | 14/03/18. |
| **Checked by:** | TAG. | **Date:** | 15/03/2018 |