

NOTIFICATION TO STOCK EXCHANGE

COMPANY STATEMENT

U.S. FDA Classifies Biocon Biologics Site in Johor Bahru, Malaysia as Voluntary Action Indicated (VAI)

Bengaluru, Karnataka, India, January 12, 2025

“The U.S. Food and Drug Administration (FDA) has classified Biocon Biologics’ Insulins facilities in Johor Bahru, Malaysia as Voluntary Action Indicated (VAI).

“This relates to the cGMP inspection conducted by the agency between September 15 – 27, 2024. The inspection scope had included several biologics manufacturing units comprising one (1) Drug Substance and one (1) Drug Product manufacturing units, one (1) Medical Device Assembly unit, one (1) Analytical Quality Control Laboratory, two (2) Microbiological Control Laboratories and two (2) Warehouses.

“Biocon Biologics remains committed to global standards of Quality and Compliance.”

– *Company Spokesperson*

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