

Evaluation Certificate

Certificate Number:BSL-V20231114ERES-A01

This is to certify that:

Company: Beijing HollySys Intelligent Technologies Co., Ltd.
Address: No.2 Di Sheng Middle Road, Economic-Technological Development Area 100176 Beijing, China
Product: HT8001CN(software version: 3.0.39)
Brand: HollySys

Description:

The HollySys HT8001CN software is used for managing production equipment of pharmaceutical industry by configuration.

The software was evaluated by BSLI with respect to the following standards and requirements:

- »product specification«
- »Eudralex Volume 4, Annex 11, Computerized systems«
- »FDA 21 CFR Part 11, Electronic Records; Electronic Signatures«

The software complies with FDA 21 CFR Part 11, a Compliance White Paper provides a detailed description how HT8001CN of HollySys conforms to FDA 21 CFR Part 11 and Eudralex Volume 4, Annex 11. The relevant compliance function test results refer to CSV-HT8001CN-FAT-002 FAT Report.

This certificate does not make representations or warranties to any person or entity other than the named certificate holder, it is issued for record keeping purpose only.



(CSV Consultant : Yanhong Zhu)



(Authorized officer : Juncheng Wei)

Beijing, January 24, 2024

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