

CERTIFICATE

SYSTEM/SOFTWARE VALIDATION

Name: M/s Nihaar Equipment Pvt. Ltd. (Mumbai)

System/Software: NIV-DAS Version 2.1.1 (Web)

Tangent Group of Companies (M/s Tangent Technologies / M/s TangentTech Infosoft Pvt. Ltd.) has validated NIV-DAS Software version 2.1.1 (Web) developed by M/s Nihaar Equipment Pvt. Ltd.

Tangent Group of Companies (M/s Tangent Technologies / M/s TangentTech Infosoft Pvt. Ltd.) found the quality status of NIV-DAS Software version 2.1.1 (Web) is traceable from the qualification documents, In addition, the hardware supplied with the NIV-DAS Software version 2.1.1 (Web) has been tested against NIST traceable Standards according to established procedure to ensure that its performance meet specifications.

To support this certification for GLP/GMP Requirements of this software product the below mentioned documents has been taken into consideration for validation of system.

- Functional / Design Specification
- Risk assessment
- Software/Hardware Revision History
- 21 CFR part 11 Requirements
- Installation / Operational / Performance Qualifications

Tangent Group of Companies (M/s Tangent Technologies / M/s TangentTech Infosoft Pvt. Ltd.) will maintain possession of all documents and their reproductions and may require a non-discloser agreement to be provided by those requiring access to these documents only use for regulatory Inspection/authorities.

Dated 26-03-2025

Jayesh Patel

Tangent Group of Companies

(M/s Tangent Technologies /

M/s TangentTech Infosoft Pvt. Ltd.)

Managing Director

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