

CERTIFICATE

SYSTEM/SOFTWARE VALIDATION

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

System/Software: NIV-DAS Version 2.0 (Web)

M/s Tangent Technologies has validated NIV-DAS Software version 2.0 (Web) Developed by M/s Nihaar Equipment Pvt. Ltd.

M/s Tangent Technologies found the quality status of NIV-DAS Software version 2.0 (Web) is traceable from the qualification documents, In addition, the hardware supplied with the NIV-DAS Software version 2.0 (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

M/s Tangent Technologies 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 04-07-2018

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