

blue inspection GmbH confirms the following:

The company:

Infraserv GmbH & Co. Höchst KG

Site:

Industriepark Höchst
65926 Frankfurt am Main

has been audited in accordance with applicable GMP requirements on
29.10.2024 and 04.11.2024 – 05.11.2024.

Audited areas:

- General GMP-System ISH-Gruppe
- Technical Gases (Oxygen, Nitrogen, compressed Air, Hydrogen)
- Purified Water (generation and testing)
- Ammonia (liquid, water, gas) as raw material
- Facilities Services (building G 830)
- Laboratory Umwelt-und Prozessanalytik
- IT-Infrastructure and applications (PRISMA, ZEUS, SAPPM)

The results of the audit are laid down in the inspection report:
181684_INFRA SERV_01 (dated 28-FEB-2025).

The CAPA-plan (dated 11-MAR-2025) addressing the observations was assessed as adequate by the lead auditor. CAPA implementation should be verified during the next audit. From the knowledge gained during the audit and the assessment of the CAPA plan, it is considered that the company complies with applicable GMP requirements.

This certificate reflects the status of the site at the time of the audit noted above and should not be relied upon to reflect the compliance status if more than 3 years have elapsed since the date of that audit. The authenticity of this certificate may be confirmed by blue inspection GmbH upon consultation.

This certificate is valid until: 05.11.2027

Dr. Norbert Waldöfner (Lead Auditor)

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