

blue Inspection body confirms the following:

The company:

Infraserv Höchst Gruppe
Infraserv GmbH & Co. Höchst KG
Industriepark Höchst
65926 Frankfurt am Main

Subsidiaries

- Infraserv Logistics GmbH
- Provalidis - Partner für Bildung und Beratung GmbH

has been audited in accordance with applicable GMP requirements on
05-NOV-2018 – 07-NOV-2018

Audited areas:

- Technical Gases (Oxygen, Nitrogen, Compressed Air, Hydrogen as Excipient)
- Purified Water as Excipient
- Ammonia (liquid) as raw material
- UPA Laboratory
- Facility Management (building H 769)
- Infraserv Logistics (Storage) GMP / GDP
- Provalidis (E-Learning)

The results of the audit are laid down in the inspection report:
BLUE-IRN-2018-11-05-01-INFRA SERV.

The CAPA-plan addressing the observations (dated 06-FEB-2019) 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 body upon consultation.


Gert Heimann, Managing Partner

Münster, 15-MAR-2019

blue inspection body GmbH, Hafenweg 18-20, 48155 Münster, Germany

This certificate is valid until: 15-MAR-2022