

Compliance Statement: Blue Line Pharmaceutical Hardware Solutions

Subject: Compliance with EU GMP, FDA, and ISO 14644 Standards

Products: Blue Line pharmaceutical product lines: HMI, Cleanroom Tablets, and Mobile Operator Stations

Updated: March 23, 2026

1. Purpose

This document confirms that Blue Line A/S pharmaceutical hardware solutions, including HMIs, cleanroom tablets, and mobile operator stations, are designed and manufactured to meet the stringent requirements of the life science and pharmaceutical industries. Our products support compliance with global regulatory standards for use in cleanroom environments.

2. EU GMP Annex 1 Compliance

Blue Line hardware is engineered to support production in the cleanroom grades A, B, C, and D (corresponding to ISO 5 to ISO 8) environments as defined in EU GMP Annex 1.

- **Cleanability:** All surfaces are smooth, non-porous, and resistant to aggressive cleaning agents (e.g., IPA, HP/VHP, Spor-Klenz).
- **Design:** The fanless design prevents air turbulence and the spread of particles, which is critical for maintaining the integrity of cleanroom grades A, B, C, and D (corresponding to ISO 5 to ISO 8)
- **Materials:** We use high-quality such as PEEK, AISI 304 or 316L stainless steel, ensuring no corrosion or particle shedding over time with respect to Airborne Molecular Contamination (AMC).

3. FDA Compliance (21 CFR Part 11 & cGMP)

Blue Line products facilitate customers' adherence to FDA 21 CFR Part 11 and Current Good Manufacturing Practice (cGMP) regulations.

- **Hygienic design:** The hardware features a "no-gap" design, eliminating crevices where bacteria or contaminants can accumulate, meeting FDA requirements for pharmaceutical equipment.

- **Data Integrity:** Our systems support secure login, biometric scanners (optional), and audit trail integration, enabling the technical controls necessary for electronic record-keeping.

4. ISO 14644 Classification

Blue Line products are tested and verified for use in cleanrooms classified according to ISO 14644-1.

- **Particle Emission:** Due to sealed, fanless construction and choice of materials, our units are suitable for use in cleanroom grades A, B, C, and D (corresponding to ISO 5 to ISO 8).
- **Material Outgassing:** Components are selected to ensure minimal outgassing, maintaining the purity of the cleanroom air.

5. Summary of Key Features

- **Stainless Steel Construction:** AISI 304/316L for maximum durability and hygiene.
- **Full Flush Fronts:** Multi-touch screens are integrated with no gaps for easy disinfection.
- **Chemical Resistance:** Tested against verified pharmaceutical detergents including VHP.
- **Mobile Flexibility:** Mobile operator stations are designed with cleanroom-grade casters and integrated battery solutions for seamless operation across different cleanroom grades.