

HYGIENE CONFORMITY



Manufacturer:

GERHMAN ENDÜSTRİ TEKNOLOJİLERİ SAN. VE TİC. LTD. ŞTİ.

Address: SANİYE ERMUTLU SK. ÇOLAKOĞLU PLAZA NO: 12/2 KOZYATAĞI-KADIKÖY/ İSTANBUL, TURKEY

Product:

HEALTHCARE ZONE AND OPERATION ROOM EQUIPMENT

Model/Type:

Impilo, Salus-X, Purus

Assessment Center: ASTOR MAYER LABORATORY INSPECTION CERTIFICATION AND TRAINING SERVICES LTD. STI. Atalar Mah. Muslu Sok. No:3/1 Kartal İstanbul/TURKEY

Product Certification Standard(s):

VDI 6022 Blatt 1:2018 Ventilation and indoor-air quality - Hygiene requirements for ventilation and air-conditioning systems and units - Requirements for underground components (VDI Ventilation Code of Practice) Hygiene in air-conditioning systems

VDI 3803 Blatt 1:2020 Air-conditioning - Structural and technical principles - Central air conditioning systems (VDI Ventilation Code of Practice)

DIN 1946-4:2018 Ventilation and air conditioning - Part 4: Ventilation in buildings and rooms of health care

BS EN 17141:2020 Cleanrooms and associated controlled environments. Bio contamination control

EN 15780:2011 Ventilation for buildings - Ductwork - Cleanliness of ventilation systems

Type of Material:

Guard: Galvanized Steel; Pitot: Brass (Cu, Pb, Fe, Sn, Al, Ni, Zn); Dye: RAL 9010 electrostatic application of powdered paint; Filter fixing device: stainless, bakelite; Pitot bearing: galvanized rivet (rivet nut round, body steel flange head)

AISI 304 stainless steel; High efficiency particulate absolute (HEPA Filter): HHS-H13-M20-305x610-FW/P (Dimensions (mm) 305x610x292, Class According to EN 1822 H13, Ap Initial (Pa) 240, Min. Efficiency at MPPS (%) 99.95, Aerosol Type DEHS; Laminisator: Aluminum profile; Textile (cloth): Polyester Mesh AISI 304 stainless steel; Filter: Description: Synthetic filters for air, Content: Air filter made with thermos bond fibers, Filtration class: G3

Production Control Report and Date:

Report No: TR-0726.103 Inspection Report Date: 23.07.2026

Audit Date: 19.06.2026-13.07.2026

Test report: TR-23.07.203-1 with TR-23.07.203-9 and TR-23.07.204

In conclusion it can be stated that the examined Hygienic Equipment, as specified in the test report TR-23.07.203 and TR-23.07.204, is in compliance with the above mentioned regulations. Within the framework of the hygiene conformity testing, the hygienically relevant constructive requirements were tested in accordance with the afore mentioned regulations. Further test perimeters: microbiological material testing, testing of the cleaning and disinfectant resistance, testing of the instructions for use and the regular, at least annual, hygienic production monitoring of the components by the ASTOR MAYER CERTIFICATION LLC. The test was conducted with regard to hygienic aspects of the specified regulations only. However, the hygiene conformity testing does not include toxicological and sensory testing of the materials. In the context of the hygiene - conformity check the hygienic relevant requirements of the above-mentioned guidelines were tested. Requirements of other guidelines, which refer to the above-mentioned guidelines, were not tested. Furthermore, the hygiene - conformity check does not cover toxicological and sensorial tests of the used materials. The document is valid as long as the Client complies with the terms of the contract, undergoes annual surveillance audits and maintains the relevant requirements pursuant to International accreditation rules. Certificate validity status can be queried at www.astormayer.com.

Certificate No : HYG-W-23.07.202
Certificate Date : 25.07.2023
Issue Date : 24.07.2026
Validity Period : 1 year
Expiry Date : 24.07.2027

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1309 Coffeen Avenue STE 10372 Sheridan, Wyoming 82801 United States of America The document is valid as long as the Client complies with the terms of the contract, undergoes annual surveillance audits and maintains the relevant requirements pursuant to International accreditation rules. Certificate validity status can be queried at www.astormayer.com

Approved

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Hygienic Products

