valid until: December 6, 2029

Fraunhofer

TESTED®
DEVICE

Parteco S.r.l.
Parteco PST and CIS system
Report No. PA 2410-1571

Statement of
Qualification

Single product
Hygienic Design

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Statement of Qualification · Single product

Customer

PARTECO S.r.l.
via L. Negrelli, 65/67
20851 Lissone
Italy

Component tested

Category: Cleanroom Facilities

Subcategory: Wall/Ceiling/Floor/Door

Product name: Parteco PST and CIS system (manufacturing date: 10/2024; color ceiling panel: RAL9010); includes the following objects

- PST.LAF / PST partition wall panel constructed with High Pressure Laminate (HPL) having melaminic aminoplastic resins exposed surface
- Anodized aluminium profiles
- Polycarbonate 3-way joints for profiles, polyester powder coated
- VC33TS window with double 3+3 safety glasses
- B1PSI / door with High Pressure Laminate (HPL) leaf panel, anodised aluminium doorframe with EPDM gasket seal, hidden hinges and floor seal
- CIS.ACC false ceiling constructed with anodized aluminium profiles frame and PVC pre-coated steel ceiling panels
- U-seal 550FC / Sealant

Assessment of conformity to GMP regulations as well as to EHEDG conception and design recommendations

Standards/Guidelines: EU GMP Annex 1; EHEDG Doc. 8; DIN EN 1672-2; ISO 14159
The norms stated generally refer to the version valid at the time of the tests.

Assessment criteria:

- Materials utilized
- Material pairings
- Installed components
- Geometries of components used
- Joining methods
- Detailed constructional solutions
- Manufacturing processes
- Surface coatings/coating systems

The suitability of the operating utility for use in a GMP-conform manufacturing environment is ascertained on the basis of the assessment of these criteria with the aid of expert knowledge. The assessment focuses mainly on the avoidance of contamination as well as on the ability to clean and disinfect the operating utility.

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Test result / Classification

The Parteco PST and CIS system is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:

Suitability
up to GMP Class A / B

However, this only applies to the tested operating utility in a resting state. An overall reassessment would need to be made after installation in a manufacturing environment.

The measuring devices used for the qualification tests are calibrated at regular intervals; their results can be traced back to national and international standards. In cases where no national standards exist, the test procedure implemented complies with the technical regulations and norms applicable at the time of the test. The relevant documentation can be viewed on request at any time.

Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA

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-- — Place, current date

on behalf of
Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA

This document only applies to the named product in its original state and is valid for a period of 5 years from the date the first document was issued. The document can be verified under **www.tested-device.com**.

DUPLICATE