



The first cleanroom system certified

Parteco PST and CIS system



www.parteco.it

Parteco, the leading Italian company in the design, manufacturing, and installation of cleanroom systems since 1974.

The cleanroom systems are manufactured at Parteco's production facilities using highly automated processes, all while being closely monitored by skilled personnel who ensure meticulous attention to detail and finishes—qualities that are a hallmark of "Made in Italy" products.

Parteco holds ISO 9001 certification for its quality management system, as well as ISO 45000 certification for its safety management.

Parteco is continually evolving. Our research and development team is dedicated to discovering new solutions, materials, and advanced construction systems, ensuring that we deliver the best possible products to our customers. These solutions are aligned with the latest advancements in the life sciences and pharmaceutical industries, while fully complying with cGMP ISO 14644 and FDA requirements.

A tangible result of this dedication is the recent achievement of certificates confirming the suitability of the Parteco PST and CIS systems for use in cleanrooms, **in accordance with EU GMP Annex 1 (hygienic design) and ISO 14644-1 (particle release) standards.**

The certificates have been released from the German testing laboratory IPA Fraunhofer of Stuttgart after a numerous test on the materials (particle release), on the accuracy of the elements construction, on the quality of the cleanroom assembling and the perfect cleanability of the system (hygienic design).

Parteco is the only company on the market capable of offering, manufacturing, and installing an IPA-certified cleanroom system.





valid until: December 6, 2029

Fraunhofer
TESTED[®]
DEVICE

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

Single product
Particle Emission
in Cleanroom
(atmospheric)

Qualification Certificate

This is to certify that the product mentioned above, provided by

Parteco S.r.l.
Lissone, Italy

has been awarded a Fraunhofer certificate TESTED DEVICE bearing the report number PA 2410-1571.

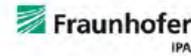
The Parteco PST and CIS system (color ceiling panel: RAL9010) was assessed in compliance with ISO 14644-14. When operated under the specified test conditions (room temperature: 22 °C ± 0.5 °C; relative humidity: 45 % ± 5 %), it is suitable for use in cleanrooms fulfilling the specifications of the following Air Cleanliness Classes according to ISO 14644-1:

Test parameter(s)	Air Cleanliness Class
Structure-borne noise = approx. 30 Hz: Inside measurement	2
Structure-borne noise = approx. 50 Hz: Outside measurement	1
Overall result	2

Please note: Transport damages, incorrect installation, aging behavior, corrosion, etc. can influence the test result.

PA 2410-1571 Stuttgart, December 6, 2024
Report No. Test document Rev. 001 of Test document issued

Report No. Current document: PA 2410-1571
Date: Current Date: *[Signature]*
on behalf of: Frank Burger, Project Manager Fraunhofer IPA
Dr.-Ing. Frank Burger, 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.
Detailed information and parameters of the test environment can be found in the Fraunhofer IPA test report.



valid until: December 6, 2029

Fraunhofer
TESTED[®]
DEVICE

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

Single product
Hygienic Design

Qualification Certificate

This is to certify that the product mentioned above, provided by

Parteco S.r.l.
Lissone, Italy

has been awarded a Fraunhofer certificate TESTED DEVICE bearing the report number PA 2410-1571.

The Parteco PST and CIS system (color ceiling panel: RAL9010) is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:

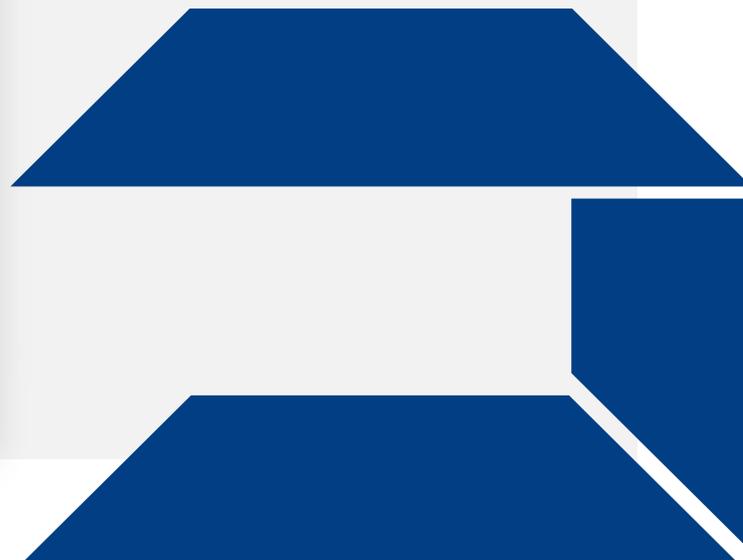
Suitability
up to GMP Class A/B

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

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Partition Wall PST.LAF: Modular, freestanding panels made of 4mm HPL exposed surfaces and an inner insulation core made of rockwool, aluminum honeycomb, or self-extinguishing styrene. The panel surfaces are flush, and the panels are seamlessly joined and sealed with a special cleanroom sealant.

The connection structure between the modules ensures a perfectly smooth surface that is easy to clean and aesthetically pleasing. It guarantees airtight joints while allowing for the easy removal of individual panels when needed.

VC33TS windows: Designed for walls and door leaves, these windows are made of double 3+3mm safety glass with an interposed desiccant channel filled with hygroscopic salts to prevent moisture buildup between the inner panes.

Doors BP1SI: a series made of robust door leaf panels with 4mm HPL exposed surfaces, and a core identical to that of the wall panels. The doorframe and door-post frame are made of anodized aluminum profiles with a special shape to allow for easy cleaning. It includes an EPDM gasket to ensure good airtightness and stainless-steel ironmongery such as handles and push plates.

Finishing profiles: a specially designed anodized aluminum profile system for ceilings, walls, and corners ensures excellent connections at every angle, as well as vertical and horizontal joints. This system allows for quick and easy installation while avoiding recessed areas that are difficult to clean.

CIS.ACC: a modular suspended ceiling with an anodized aluminum profile grid frame system. The panels are made of PVC-coated steel sheets, shaped to fit the dimensions of the ceiling grid frame. The modular ceiling can easily accommodate LED lighting fixtures of various sizes, LED strips where needed, as well as air diffusers and filter elements of any type. Ceiling panels can also be equipped with dedicated thermal insulation layers.



 **PARTECO**
Modular Cleanroom System



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