



Fraunhofer

TESTED[®] DEVICE

DYNACO EUROPE NV
Dynaco D-313 CR LF
Report No. DY 2508-1659

DUPLICATE

Statement of
Qualification

Single product
Hygienic Design

Statement of Qualification · Single product

Customer	DYNACO EUROPE NV Waverstraat 21 9310 Moorsel Belgium
Tested product	
Category:	Cleanroom Facilities
Subcategory:	Wall/Ceiling/Floor/Door
Product name:	Dynaco Europe D-313 Cleanroom LF (manufacturing date: 7/2025; color curtain: white; dimensions: 2000mm x 2300mm; article number: D-313 Cleanroom LF; serial number: BBA2503298 (DY311))

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.

Test result / Classification

The door Dynaco Europe D-313 Cleanroom LF 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 C

However, this only applies to the tested system in a resting state; an overall assessment of the manufacturing environment would need to be made after its installation.

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	DY 2508-1659 Report No. first document	Stuttgart, October 2, 2025 Place, date of first document issued
Business unit Testing and Certification	-- Report No. current document	-- Place, current date
Nobelstrasse 12 70569 Stuttgart Germany	on behalf of Dr.-Ing. Frank Bürger, head of business unit Testing and Certification	