



Fraunhofer

TESTED[®] DEVICE

Roxtec International AB
LABSEAL C LTX

Report No. RO 2508-1666

DUPLICATE

Statement of
Qualification

Single product
Hygienic Design

Statement of Qualification · Single product

Customer	Roxtec International AB Rombvägen 2 37165 Lyckeby Sweden
Tested product	
Category:	Cleanroom Facilities
Subcategory:	Wall/Ceiling/Floor/Door
Product name:	LABSEAL C LTX WITH COUNTER FRAME 0-40 (manufacturing date: fourth quarter of 2024; color: white; article number: 241407)

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 LABSEAL C LTX WITH COUNTER FRAME 0-40 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 for the tested operating utility when in a resting state and 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	RO 2508-1666 Report No. first document	Stuttgart, September 24, 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	