



valid until: June 19, 2031

Fraunhofer

TESTED[®] DEVICE

Glamox AS
C61

Report No. GL 2604-1769

DUPLICATE

Statement of
Qualification

Product series
Hygienic Design

Customer	Glamox Sp. z o.o. ul. Jagiellońska 51 32 – 410 Dobczyce Poland
Tested product	
Category:	Cleanroom Facilities
Subcategory:	Lighting Systems
Product name:	C61 Tested Products: - C61-S565X565 8000 DALI 940 MP/GL (manufacturing date: 4/14/2026) - C61-R600x600 5000 HF 840 C1 OP/PC (manufacturing date: 4/8/2026)

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 luminaire series C61 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 device may only be used in GMP Class A or B when it is certain that the geometry of the large-surface lamp does not impair the quality of the laminar flow.

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.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA

Business unit
Testing and Certification

Nobelstrasse 12
70569 Stuttgart
Germany

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on behalf of 	
Dr.-Ing. Frank Bürger, head of business unit Testing and Certification	