



Fraunhofer

TESTED[®]
DEVICE

Zumtobel Lighting GmbH
SUPREME RECESSED TOP-REVISION
Report No. ZU 2503-1608

DUPLICATE

Statement of
Qualification

Product series
Hygienic Design

Customer	Zumtobel Lighting GmbH Schweizerstrasse 30 6850 Dornbirn Austria
Tested product	
Category:	Cleanroom Facilities
Subcategory:	Lighting Systems
Product name:	SUPREME RECESSED TOP-REVISION Tested Product: <ul style="list-style-type: none">SUPREME RECESSED TOP-REVISION CL2 ST 6600-840 M625Q SG MP LDO (manufacturing date: 3/11/2025)

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:	<ul style="list-style-type: none">Materials utilizedMaterial pairingsInstalled componentsGeometries of components usedJoining methodsDetailed constructional solutionsManufacturing processesSurface coatings/coating systems <p>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.</p>

Test result / Classification	The luminaire series SUPREME RECESSED TOP-REVISION is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:
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Suitability
up to GMP Class C

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment can only be made after its installation in the production 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	ZU 2503-1608 Report No. first document	Stuttgart, May 26, 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	