



Fraunhofer

**TESTED[®]
DEVICE**

BUCK d.o.o.
ETNA CR DO

Report No. BU 2011-1188

DUPLICATE

Statement of
Qualification

Single product
Hygienic Design

Customer	BUCK d.o.o. Milorada Jovanovica 9 11147 Belgrade Serbia
Component tested	
Category:	Cleanroom Facilities
Subcategory:	Lighting Systems
Product name:	ETNA CR DO (manufacturing date: 5/14/2020; color: white; batch number: RN20/01791; serial number: 1020315; size: 640/640/105 mm)

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 ETNA CR DO 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 recommendation only pertains to the operating utility when in a resting state. An overall assessment of the luminaire ETNA CR DO can only be made after its installation in the production line.

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	BU 2011-1188 Report No. first document	Stuttgart, March 17, 2021 Place, date of first document issued
Department of Ultraclean Technology and Micromanufacturing	-- Report No. current document	-- Place, current date
Nobelstrasse 12 70569 Stuttgart Germany	on behalf of Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA	