



valid until: March 6, 2031

Fraunhofer

TESTED[®] DEVICE

EAE Lighting
BLOOM IP65 60x60
Report No. EA 2602-1723

DUPLICATE

Statement of
Qualification

Single product
Hygienic Design

Statement of Qualification · Single product

Customer
EAE ELEKTRİK AYDINLATMA ENDÜSTRİSİ SANAYİ VE TİCARET ANONİM ŞİRKETİ
Organize Sanayi Bölgesi (Makina İhtisas OSB) Mah. 14.Sk. Fabrika Binası (A+B+C Blok) No:3/1 41455 Dilovası/KOCAELİ
Turkey

Tested product
Category: Cleanroom Facilities
Subcategory: Lighting Systems
Product name: BLOOM V3 IP65, Recessed Mounted 60x60cm 36 W LED Luminaire (manufacturing date: 12/2/2025; color: white; article number: 3181655; serial number: 5139565120001)

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 BLOOM V3 IP65, Recessed Mounted 60x60cm 36 W LED Luminaire 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 D

However, this only applies to the tested system in a resting state and requires an overall assessment of the manufacturing environment after 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.

Fraunhofer Institute for Manufacturing Engineering and Automation IPA

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Report No. first document

Stuttgart, March 6, 2026
Place, date of first document issued

Business unit
Testing and Certification

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Report No. current document

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Place, current date

Nobelstrasse 12
70569 Stuttgart
Germany

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