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DEVICE

REGIOLUX GmbH
ADAMP/1500 LED 12500 IPA
Report No. RE 2011-1189

Statement of
Qualification

Single product
Hygienic Design

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IPA

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Statement of Qualification · Single product

Customer

Regiolux GmbH
Hellingerstrasse 3
97486 Königsberg
Germany

Component tested

Category: Cleanroom Facilities

Subcategory: Lighting Systems

Product name: ADAMP/340-1500 LED 12500 940 DALI IP65
(manufacturing date: week 43/2020; color: traffic white; serial number: 62154026670)

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 ADAMP/340-1500 LED 12500 940 DALI IP65 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

The recommendation takes the existing of the PE foam seal into consideration, which slightly jut out over the edge of the luminaire. A release of particles can be observed at this point.

However, this recommendation only pertains to the operating utility when in a resting state. An overall assessment of the ADAMP/340-1500 LED 12500 940 DALI IP65 can only be made after its installation in the production area.

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

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on behalf of
Dr.-Ing. Frank Bürger, Project Manager Fraunhofer IPA

This document only applies to the named product in its original state and is valid for a period of 5 years from the date the first document was issued. The document can be verified under **www.tested-device.com**.