Cleanroom (atmospheric)

valid until: August 15, 2030

Fraunhofer

TESTED®
DEVICE

CAITRON GmbH
Cleanroom HMI series
Report No. CA 2505-1630

Statement of
Qualification

Product series
Hygienic Design

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Statement of Qualification · Product series

Customer

CAITRON GmbH
Gewerbepark Edelweiss 4
88138 Weissensberg
Germany

Tested product

Category: Working Place and Operator

Subcategory: Work Equipment

Product name:

Cleanroom HMI series
(color: black/stainless steel)
consisting of the following components:

- CR24-24" Cleanroom HMI
  manufacturing date: 3/3/2025; dimension: 400 x 597 x 69 mm; material: V4A steel; article number: CAPPT24D5-00117)
- CR17-17" Cleanroom HMI
  (manufacturing date: 10/22/2024; dimension: 315 x 447 x 64 mm; material: V4A steel; article number: CAPPT17A1-00001)
- HSH laboratory workstation/table mounting
  (manufacturing date: 4/21/2025; article number: 101 393)

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.

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Test result / Classification

The Cleanroom HMI series 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 A

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 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

Business unit
Testing and Certification

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

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**.