

# Fraunhofer

## TESTED<sup>®</sup> DEVICE

CAITRON GmbH Surface Tablet CT13 **Report No. CA 2505-1630** 

Statement of Qualification

Product series **Hygienic Design** 





## **Statement of Qualification** • Product series

Customer CAITRON GmbH

> Gewerbepark Edelweiss 4 88138 Weissensberg

Germany

**Tested product** 

Working Place and Operator Category:

Work Equipment Subcategory

CAITRON Surface Tablet CT13 Product name:

(manufacturing date: 3/5/2025; material: stainless steel; article number:

CT13S10A2-00209)

### Assessment of conformity to GMP regulations as well as to EHEDG conception and design recommendations

Standards/guidelines:

Assessment criteria:

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.

- 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 CAITRON Surface Tablet CT13 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 And Buil

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