

# Fraunhofer

## TESTED<sup>®</sup> DFVICF

ads-tec Industrial IT SHW9000

Report No. AD 2507-1652

Statement of Qualification

Product series **Hygienic Design** 





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

**Customer** ads-tec Industrial IT GmbH

Heinrich-Hertz-Strasse 1 72622 Nürtingen Germany

**Tested product** 

Category: Working Place and Operator

Subcategory: Work Equipment

Product name: SHW9000
Tested Products:

• Smart Hygienic Panel 9019 (manufacturing date: 4/2025)

• Smart Hygienic Panel 9024 (manufacturing date: 4/2025)

### 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.



#### Test result/Classification

The Smart Hygienic Panels series SHW9000 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 only applies to the tested operating utility in a resting state. An overall assessment of the manufacturing environment would need to be made after its 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.

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 River

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.