



# Fraunhofer

## TESTED<sup>®</sup> DEVICE

POUL Group ApS  
the fork (P-FORK-P1)  
**Report No. PO 2510-1679**

DUPLICATE

Statement of  
Qualification

Single product  
Hygienic Design

# Statement of Qualification · Single product

## Customer

POUL Group ApS  
Ålandsgade 26, 4. mf.  
2300 Copenhagen  
Denmark

## Tested product

Category: Automation Components  
Subcategory: Robotics  
Product name: the fork (P-FORK-P1)  
(manufacturing date: 8/15/2025; color: gray/blue; dimensions: 1650 x 900 x 700 mm; article number: P-FORK-P1)

## 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 fork (P-FORK-P1) is principally suitable for use in hygienic areas up to the following GMP Class according to EU GMP Annex 1:

<b>Suitability</b>
<b>up to GMP Class C</b>

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 a manufacturing environment.

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

PO 2510-1679  
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Business unit  
Testing and Certification

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Report No. current document

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Germany

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