



# Fraunhofer

## TESTED<sup>®</sup> DEVICE

Gimatic S.R.L.  
KIT-GMPLM3240  
**Report No. GI 2404-1518**

DUPLICATE

Statement of  
Qualification

Single product  
Hygienic Design

# Statement of Qualification · Single product

## Customer

Gimatic S.R.L.  
Via Enzo Ferrari 2/4  
25030 Roncadelle (BS)  
Italy

## Component tested

Category: Automation Components  
Subcategory: Positioning Systems  
Product name: GMP kit for long stroke parallel grippers (KIT-GMPLM3240)  
(manufacturing date: 8/24/2023; color: black/clear; batch number: ODL-AC12019)

## 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 GMP kit for long stroke parallel grippers (KIT-GMPLM3240) 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/B

However, this only applies to the tested system in a resting state; an overall assessment of the manufacturing environment would need to be made after its installation.  
Care must be taken to clean and check the silicon cover at regular intervals.

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

GI 1904-1109  
Report No. first document

Stuttgart, June 6, 2019  
Place, date of first document issued

Department of Ultraclean Technology and Micromanufacturing

GI 2404-1518  
Report No. current document

Stuttgart, June 6, 2024  
Place, current date

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on behalf of   
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