



Fraunhofer

**TESTED[®]
DEVICE**

Gimatic S.r.l.
Gripper MPPM1606-KIT-GMP
Report No. GI 1410-728

DUPLICATE

Statement of
Qualification

GMP

Statement of Qualification

Customer: Gimatic S.r.l.
Via Enzo Ferrari, 2/4
25030 Roncadelle - Brescia
Italy

Component tested

Category: Automation Component

Subcategory: Positioning System

Product name: Parallel gripper MPPM1606-KIT-GMP
(Lot-No.: ODL-S02845; manufacturing date: 7/8/2014; color: black/clear)

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 refer to the relevant editions applicable 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:

(in acc. with EU GMP Annex 1)

The parallel gripper MPPM1606-KIT-GMP manufactured by Gimatic S.r.l. was modified subsequent to the assessment, taking into account the majority of design recommendations. The optimized silicon cover now enables the interior and the exterior of the gripper to be kept well-separated from one another. The overall design of the gripper now fulfills requirements for use in clean and hygienic manufacturing conditions.

Based on the constructional features of the GMP gripper which was assessed at Fraunhofer IPA, it has been declared suitable for use in clean and hygienic manufacturing environments on consideration of the aforementioned optimization potentials. The assessment is based on the almost full ability to clean and disinfect MPPM1606-KIT-GMP and – with only a few exceptions – the fulfillment of conception and design recommendations made by EHEDG, ISO 14159 and 1672-2.

The parallel gripper MPPM1606-KIT-GMP meets requirements for use in clean and hygienic manufacturing environments. In principle, the gripper is declared suitable for use in hygienic areas fulfilling max. GMP Cleanliness Class A/B. 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.

For further information about the test environment and parameters, please refer to the Fraunhofer IPA test report.

Fraunhofer Institute for
Manufacturing Engineering and Automation IPA

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and Micromanufacturing

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i. A. 
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