



Fraunhofer

**TESTED[®]
DEVICE**

ABB Engineering (Shanghai) Ltd.

IRB1200-7 / 0.7

Report No. AB 1507-774

DUPLICATE

Statement of
Qualification

Hygienic Design

Statement of Qualification

Customer	ABB Engineering (Shanghai) Ltd. No. 5, Lane 369, Chuangye Road 201319 Pudon District, Shanghai China
Component tested	
Category:	Automation Component
Subcategory:	Robotics
Product name:	IRB1200-7/0.7 (date of manufacturing: 19/9/2014; color: white; serial number: 1200-900002; cleanroom sealing on axis 5; member of the IRB1200 M2004 family)

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:	<ul style="list-style-type: none">• 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

Due to the constructional features of the robot system IRB1200-7/0.7 investigated at Fraunhofer IPA, and under consideration of the optimization potentials listed, the robot is declared suitable for use in clean and hygienic manufacturing areas. The assessment is based on the almost total ability to clean and disinfect the robot system and– with only a few exceptions – compliance with the conception and design recommendations of EHEDG, ISO 14159 and 1672-2.

Suitability
Hygienic areas up to GMP Class C

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.

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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Place, date of first document issued

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Place, current date

on behalf of 
Frank Bürger, Project Manager Fraunhofer IPA