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**TESTED[®]
DEVICE**

DENSO WAVE Inc.
Robot VS050S2-AV6-R1
Report No. DE 1409-725

DUPLICATE

Statement of
Qualification

GMP

Statement of Qualification

Customer

DENSO WAVE Inc.
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Japan

Component tested

Category: Automation components
Subcategory: Robotics
Product name: Robot series VS050S2-AV6-R1
(manufacturing date: 1/2015; serial number: 01S149R; weight: 38 kg)

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)

In principle, the robot series VS050S2-AV6-R1 is declared suitable for use in hygienic areas up to the highest cleanliness level of GMP Cleanliness Class A. However, this only applies for the tested operating utility when in a resting state; an overall assessment would need to be made after 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.

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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