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**TESTED<sup>®</sup>  
DEVICE**

DENSO WAVE Inc.  
Robot VS050S2-AV6-R1  
**Report No. DE 1511-792**

DUPLICATE

Statement of  
Qualification

Riboflavin Test  
(Equipment)

# Statement of Qualification

## Customer

DENSO WAVE Inc.  
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470-2297 Aichi  
Japan

## Component tested

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

## Cleanability test (riboflavin test)

Standards/Guidelines: VDMA information sheet »Riboflavin test for low-germ or sterile process technologies – Fluorescence test for examination of cleanability«. The norms stated refer to the relevant editions applicable at the time of the tests.

Test environment parameters: Laboratory

Test procedure parameters:

- Test solution: .....0.2 g riboflavin, 5 g hydroxethylcellulose  
.....in 1000ml ultrapure water
- Application of test solution:..... pump spray
- Drying time: ..... approx. 2-3 h
- Cleaning method:..... wiping
- Cleaning medium: .....ultrapure water
- Number of wiping cycles: ..... 3
- UV light:..... $\lambda = 366 \text{ nm}$

Cleanability can only be assessed qualitatively and is assessed based on the amount and size of defects occurring.

## Test result / Classification

The examination of cleanability of the robot VS050S2-AV6-R1 was investigated according to VDMA information test sheet. The following test result could be provided:

- The assessed cleanability of the robot system is regarded as sufficient for a subsequent safe application of validated room or isolator decontamination methods, such as vaporized hydrogen peroxide.
- The riboflavin test showed that only a few areas are not fully cleanable. All other surfaces can be cleaned effectively using a validated wiping procedure.
- Provided a user risk assessment determines the cleaning efficacy of the above-mentioned critical areas to be acceptable, the preceding cleaning process fulfills the requirement stated in ISO 13408-6 for a subsequent biodecontamination step.

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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on behalf of   
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