

# Eligibility Statement qs-STAT und solara.MP, versions 13 and 14

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# **Document History**

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# 1 Eligibility Statement for qs-STAT and solara.MP, versions 13 and 14

# 1.1 Objectives

The quality management standards require proof of the eligibility of the software used for the intended application. This applies to both the initial use and the on-going use of the software. Specifically, the requirement in section 7.1.5.2.1 of the IATF guideline 16949: 2016 reads:

"... The organisation shall ensure that the calibration/verification activities and associated records shall include the following details:

i) production-related software verification used for product and process control ...".

The standard DIN EN ISO 10012: 2003 sets out the requirements for testing and validating the software as follows:

"... The software and all updated versions shall be checked and/or validated, released for use and archived before first use. The tests shall be carried out to the extent necessary to ensure valid measurement values."

The purpose of the document is to make it easier for users of our software to carry out this eligibility test. Procedures and methods for the statistical evaluation of measurement values are documented in association and company guidelines, as well as in international technical guidelines. Many of these processes are stored in our software products such as qs-STAT®, solara.MP® and destra® in the form of evaluation configurations. The present document is intended to confirm to the best of its knowledge and belief the evaluation and calculation of the statistical parameters according to these evaluation configurations. This evidence shall be provided by comparing the calculated results with the results documented in the directives and standards.

# 1.2 Boundary conditions

Reference results for selected statistical metrics are listed in this document. This selection of characteristics is based on the scope of the reference results given in the literature or the quantities required for an assessment of the evaluation. Also, a software test cannot take into account all of the variants of the hardware and software environment, which have an influence on the computing accuracy.

Numerical results from the software occasionally differ from the specified reference results in the literature in the number of decimal places. The reason for this is that the computer-aided evaluation is expected to have more decimal places than a "manual evaluation". It should also be noted that, in contrast to a calculation by hand, the software's calculations are carried out without rounded intermediate values and only the final result output is rounded to a specified number of decimal places.

The test data sets provided cover a wide range of use cases. However, this does not cover all specific possible arrangements. If you have specific documented reference data, please contact us. We will be happy to incorporate these into future versions of the declaration of eligibility.



# 1.3 Implementation

All of the test data sets listed below are taken from the literature. **Please note that these data sets only provide correct results in combination with the correctly assigned evaluation configuration**. Internally, we test each new version against the reference data sets with the associated evaluation configurations in so-called automatic tests. This means that the reading in and evaluation, as well as the comparison with the stored reference values, is carried out automatically.

For independent and manual implementation of the eligibility verification, the reference data sets are available for download on our homepage. The evaluation configurations we deliver are write-protected and can be completely protected from any interference by appropriate user rights, so that defined requirements can always be accessed under these conditions.

# 1.4 Results

In order to assist you in carrying out the proof of eligibility, we have provided further supporting documents for numerical validation on our homepage, in which we have presented the results of the statistical characteristics of the software with their relative error to the reference result. Why do such deviations occur? As already mentioned in the section "Boundary conditions", deviations in the number of decimal places can generally be attributed to different roundings. Our software products qs-STAT®, solara.MP® and destra® expect significantly more decimal points than is usual for a manual calculation. Also, internal interim values are not rounded. Only the final result is rounded by the software to the specified number of decimal places.

Data set	Evaluation configuration	Procedures and characteristic
		values
BOSCH_BOOKLET10_TYPE_1.dfq	BOSCH 2018   Sub-strategy Type 1	Type 1: Cg and Cgk
BOSCH_BOOKLET10_TYPE_2.dfq	BOSCH 2018   Sub-strategy Type 2	Type 2: % GRR
BOSCH_BOOKLET10_TYPE_3.dfq	BOSCH 2018   Sub-strategy Type 3	Type 3: % GRR
BOSCH_BOOKLET10_TYPE_4.dfq	BOSCH 2018   Sub-strategy Linearity	Linearity: t-test for regression
BOSCH_BOOKLET10_TYPE_5.dfq	BOSCH 2018   Sub-strategy Stability	Stability of the quality control chart
BOSCH_BOOKLET10_TYPE_6.dfq	BOSCH 2018   Sub-strategy Type 6	Attributive: Signal detection (%
		GRR)
BOSCH_BOOKLET10_TYPE_7.dfq	BOSCH 2018   Sub-strategy Type 7 Compatibility	Attributive: Fleiss-Kappa
	Mode	

#### Measurement system analysis - company policy: Bosch Volume 10 (Source [VOLUME 10])



Data set	Evaluation configuration	Procedures and characteristic values
MSA_4_AttributeStudyData.dfq	MSA Demonstration (4 Ed.) (06/2013)   Sub-strategy Risk Analysis (Cohen's Kappa)	Attributive: Cohen's Kappa
MSA_4_AttributeStudyData.dfq	MSA Demonstration (03/2020)   Sub-strategy Effectiveness Study (MSA nominal / ordinal)	Procedure for test system effectiveness (effectiveness analysis)
MSA_4_SignalDetectionData.dfq	MSA Demonstration (4 Ed.) (06/2013)   Sub-strategy Risk Analysis (Signal Detection)	Attributive: Signal detection (% GRR)
MSA_4_Type2StudyData.dfq	MSA Demonstration (03/2020)   Sub-strategy Type 2 – ARM (Total Variation)	Type 2 based on the average-range method
MSA_4_Type2StudyData.dfq	MSA Demonstration (03/2020)   Sub-strategy Type 2 – ANOVA (Total Variation)	Type 2 based on variance analysis
MSA_4_BiasStudyData.dfq	MSA Demonstration (03/2020)   Sub-strategy Bias Study (t-Test & %EV) Sigma Process	Bias (t-test for the bias) and %EV
MSA_4_LinearityStudyData.dfq	MSA Demonstration (03/2020)   Sub-strategy Linearity Study - t-Test (Tolerance)	Linearity: t-test for regression

## Measurement system - AIAG guideline Measurement Systems Analysis (source [AIAG MSA])

On our homepage you will find supporting documents for numerical validation according to the AIAG guideline. To do this, select on the homepage: "Service | Support Hotline | Enter the search term"

Enter "V13 Numerical validation in solara.MP" as the search term. A total of seven accompanying documents will appear, one for each of the cases listed in the table.

#### Process Capability Analysis - international guideline ISO/TR 11462-3: 2020 (E) (source: [TR 11462-3])

Please note the accompanying documents on our homepage

Data set	Evaluation configuration	Procedures and characteristic values
ISOTR11462_3_2020_E_Test	ISO/TR 11642-3: 2020 (E) - Part 1	For data sets 1 through 10:
Data_Fixed_Subgroup_Size.dfq		sampling parameters,
		capability indices,
		distribution time models,
		resulting distributions
ISOTR11462_3_2020_E_Test	ISO/TR 11642-3: 2020 (E) - Part 2	Control limits for the average standard deviation chart
Data_Fixed_Subgroup_Size.dfq		for the data sets Test 1 to Test 10, as well as signals
		for the process fault
ISOTR11462_3_2020_E_Test	ISO/TR 11642-3: 2020 (E) - Part 3	Control limits of the median range chart for the data
Data_Fixed_Subgroup_Size.dfq		sets Test 1 to Test 10, as well as signals for the
		process fault.
ISOTR11462_3_2020_E_Test	ISO/TR 11462-3: 2020(E) - Part 4	The control limits of the raw values chart in
Data_Moving_Subgroup_Size.dfq		combination with the moving calculated range chart for
		the data sets Test 1 to Test 10, as well as the signals
		for the process fault



On our homepage you will find supporting documents for numerical validation according to the guideline ISO/TR 11462-3: 2020 (E). To do this, select on the homepage:

"Service | Support Hotline | Enter the search term"

Enter "V13 Numeric Validation according to guideline ISO/TR 11462-3: 2020 (E)" as the search term. A total of four accompanying documents will appear, one for each of the cases listed in the table. In addition, the data sets and the evaluation strategies are available for download.

## 1.5 Sources

#### [AIAG MSA]

Automotive Industry Action Group AIAG: Measurement Systems Analysis Publication Date: June 2010 Edition: 4

### [TR 11462-3]

ISO/TR 11462-3:2020 Guidelines for implementation of statistical process control (SPC) — Part 3: Reference data sets for SPC software validation Publication Date: 2020-06 Edition: 1

#### [HEFT 10]

Robert Bosch GmbH Series of publications: Quality Assurance in the Bosch Group – Technical Statistics Volume 10 – Capability of measuring and test systems Edition: 01/2003