ELIGIBILITY STATEMENT FOR QS-STAT® | SOLARA.MP® | DESTRA® | VERSION 10/11/12

TARGET:

Standards for Quality Management concretely require a confirmation for the eligibility of the applied soft-ware for the intended application, before initial use as well as for a continuous use. IATF 16949:2016 provides the following information in chapter 7.1.5.2.1:

" ... The organization shall have a documented process for managing calibration/verification records. (…) The organization shall ensure that calibration/verification activities and records shall include the following details: … i) production-related software verification used for product and process control …"

In this context, ISO 10012:2003 mentions the testing or validation of the software: **"... Software, and any revisions to it, shall be tested and/or validated prior to initial use, approved for use, and archived. Testing shall be to the extent necessary to ensure valid measurement results. "**

With this statement, we want to support our customers in this task. Various company guidelines, reference manuals and specifications define procedures and approaches for statistical evalua-tions. These methods are available in qs-STAT®, solara.MP® and destra® in the form of evaluation strategies. This document shall confirm, in all conscience, the evaluation and calculation of statistics according to the respective evaluation strategy. Evidence is given by the comparison of the calculated values with the values that have been documented in the company guidelines, reference manuals or specifications.

BOUNDARY CONDITIONS:

The provided eligibility verification is limited to a specific selection of statistics. This selection is based on the scope of the documented reference results in

literature, and on mandatory values demanded to validate the evaluation. Please consider that the testing cannot consider all kinds of hardware and software environments which can indeed have an influence on computational accuracy.

Some decimal places of the calculated results may deviate from the references of some statistics due to improved numerical procedures. Please also consider that computer-assisted evaluations generally provide more decimal places than "manual" evaluations. Interim or final results might deviate due to rounding.

Basically, we want to indicate that the test data sets cover a wide range of applications but they cannot guarantee a complete consideration of all possible constellations. If you know of further documented reference data, we would be glad to include them into this eligibility statement.

ACCOMPLISHMENT:

All test data sets have been taken out of literature. The test procedures have been created by assigning the data sets to the evaluation configurations and the definition of the statistics. Loading and evaluating data as well as comparing them to specified reference values was an automated process.

The test data sets are available on the program CD for your own accomplishment of the eligibility verification. The provided evaluation strategies are write-protected and they can be protected against any kind of intervention by setting appropriate user rights, so that, under these conditions, you can always refer to defined requirements.

RESULTS:

All the statistics considered in the eligibility verification show no or no significant deviation from reference values. As already mentioned under "Boundary conditions", deviations in decimal places are usually caused by different rounding. The following example shows this issue based on a reference from the Measurement System Analysis manual.

The fact that qs-STAT®, solara.MP® or destra® internally calculate significantly more decimal places, of course, affects the interim and final results. This, of course, causes a "deviation" from the reference but does not restrict the eligibility of the software at all!

REFERENCE DATA:

Test_14	Type 1, tolerance-related, [5]
Test_15	Type 1, process-related, [5]
Test_16	Type 2 (ARM), [5]
Bosch_V1_ARM	Type 1, tolerance-related, [3]
Bosch_V2_ARM	Type 2, [3]
Bosch_V3_ARM	Type 3, [3]
Bosch_LIN	Linearity, [3]
Bosch_Stab	Stability, [3]
Bosch_Attributiv	Attribute, signal detection, [3]
QDAS_1BD	Type 1, tolerance-related, [1]
QDAS_2AD	Type 2, ARM, [1]
QDAS2ADV	Type 2, ARM, [1]
GC_AIAG1	Type 2, ANOVA, [1]
GC_AIAGV	Type 2, ANOVA, [1]
QDAS3ADM	Type 3, ARM, [1]
QDAS_3BD	Type 3, ARM, [1]
QDAS3ADN	Type 3, ANOVA, [1]
QDAS_3AD	Type 3, ANOVA, [1]
FORD_1	Type 1, tolerance-related, [2]
FORD_2	Type 2, ARM, [2]
FORD_3	Type 3, ARM, [2]
FORD_4	Type 4, ARM, [2]

FORD_5	Type 5, ARM, [2]
VDA5_Beispiel1	Measurement uncertainty, [6]
VDA5_Beispiel2	Measurement uncertainty, [6]
MSA_4th_Edition_Linearity_Study	Linearity, MSA, [7]
MSA_4th_Edition_Signal_Detection	Attribute, signal detection, [7]
MSA_4th_Edition_Type_2_Study	Type 2 (ARM, ANOVA), [7]
CNOMO	Phases 1 and 2, [4]
Test_01	Stability conditions, [5]
Test_02	Computational accuracy, [5]
Test_03	Control charts/capability indices, [5]
Test_04	Control charts/capability indices, [5]
Test_05	Control charts/capability indices, [5]
Test_06	Control charts/capability indices, [5]
Test_07	Control charts/capability indices, [5]
Test_08	Control charts/capability indices, [5]
Test_09	Control charts/capability indices, [5]
Test_10	Control charts/capability indices, [5]
Test_11	Control charts/capability indices, [5]
Test_12	Control charts/capability indices, [5]
Test_13	Control charts/capability indices, [5]

LITERATURE/REFERENCES:

[1] "Measurement System Capability" Reference Manual
Q-DAS GmbH (1999)

[2] Ford EU 1880 "Guideline for the Capability of. Measurement Systems and Gages" (1997)

[3] "Quality Management in the Bosch Group – Technical Statistics" series
Booklet 10 "Capability of Measurement and Test Processes" (2003)

[4] CNOMO E41.36.110.N
"Moyens de production, agrément capabilité des moyens de mesure, moyens de contrôle spécifique" (1991)

[5] Ford EU 883 B "Evaluation of SPC software" (1991)

[6] VDA Volume 5 – Capability of Measurement Processes (2nd edition 2010)

[7] MSA Measurement Systems Analysis, Reference Manual, Fourth Edition (2010)