DECISION RULE CONCERNING STATEMENTS OF CONFORMITY

According to DIN EN ISO/IEC 17025:2018 (General requirements for the competence of testing and calibration laboratories) there are requirements to clearly define decision rules. Decision rules are rules to describe how measurement uncertainty is taken into account in statements of conformity with specified requirements.

Following method will be implemented by encontec GmbH:

1. if a client requests a statement of conformity regarding a technical specification or standard (passed/ not passed or o.k. / not o.k., within specification/ outside specification) the following rules 2. to 4. are valid for that conformity evaluation.

2. If the customer provides specifications for an applicable decision rule that rule will be valid. Otherwise, 3. or 4. will be valid.

3. If the technical specification or standard sets requirements for the applicable decision rules we apply these unless otherwise specified on applicable decision rule by the customer. Otherwise, 4. will be valid.

4. If technical specifications or standards set no requirements on applying decision rules and no other requirements on an applicable decision rule are requested by the customer the following decision rule is valid.

	Case 1	Case 2	Case 3	Case 4	Case 5
measured value	4,0 µm	3,2 µm	3,0 µm	2,8 µm	2,4 µm
measurement uncertainty	± 0,5 µm				
result	o.k.	o.k.	not o.k.	not o.k.	not o.k.
o.k./ not o.k.-Risk	100%/ 0%	70% / 30%	50% / 50%	30% / 70%	0% / 100%

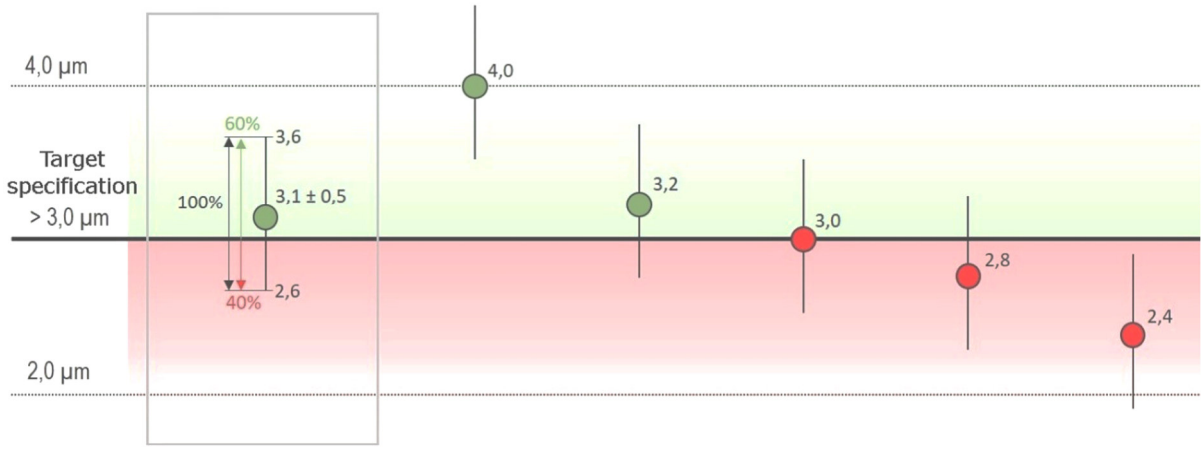

Illustration 1: exemplary depiction of the statement of conformity

Case 1: measurement is within the Limit.

Statement of Conformity: Measurement considering uncertainty is within the specification, the sample is compliant. The Risk of a wrong statement is very low.

Case 2: Measurement is within the Limit. Considering the uncertainty results in an overlap with upper or lower limit.

Conformity statement: Measurement is within the specification; the sample is compliant. Considering uncertainty, the measurement might not comply with the requirements.

The Risk of an undercut and thus a wrong statement cannot be excluded.

Case 3: Measurement is on the limit. Considering the uncertainty results in an overlap with the limit.

Conformity Statement:

a) *Target specification measurement > X:*
Measurement is on the limit and the sample is not compliant, because the specification excludes the value X itself. Considering uncertainty the measurement might comply with the specification, but the risk of an undercut and thus a wrong statement is high.

b) *Target specification measurement >= X*
Measurement is on the limit and the sample is compliant, because the specification includes the value X itself. Considering uncertainty, the measurement might not comply with the specification, but the risk of an undercut and thus a wrong statement is high.

Case 4: measured value is outside of the specification. Considering the uncertainty results in an overlap with the limit.

Conformity statement: measurement is outside of the specification and the sample is not compliant. Considering uncertainty the measurement could comply with the specification, but the risk of an undercut and thus a wrong statement is high.

Case 5: measured value is outside of the specification, even if the confidence level is considered.

Conformity Statement: Measurement including uncertainty is outside of the specification and the sample is not compliant. The risk of a wrong statement is very low.

SIGNATUR AND APPROVAL

APPROVAL BY MANAGER OF BUSINESS DEPARTMENT

13.01.2025

X i.V. Inga Bühler

Inga Bühler
PL-LL
Signiert von: Bühler, Inga