

Measurement uncertainty – decision rule according to DIN EN ISO/IEC 17025:2018

Dear customer,

According to the standard DIN EN ISO/IEC 17025:2018 (General requirements for the competence of testing and calibration laboratories), there is a requirement to determine measurement uncertainties of test results.

It is mandatory to establish decision rules for conformity assessment and to communicate them to our customers.

Decision rule - rule that describes how measurement uncertainty is accounted for when stating conformity with a specified requirement

For BIOSERV Analytik und Medizinprodukte GmbH the following decision rules are applied:

- 1) If the decision rule is defined in standards or specifications of the commissioned tests, these are deemed to be agreed with the customer.
- 2) If the customer requires a different decision rule or a separate requirement for the test result, he must communicate this separately in writing with the order enquiry/order and indicate the relevant decision case in accordance with this document.
- 3) If the above-mentioned points 1 and 2 are not available, the following decision rule is generally applied:

Decision rule according to point 3:

No measurement uncertainties are taken into account in the statement of conformity. The requirement is considered to be fulfilled if the measured value is smaller or equal to the tolerance limit or limit value.

If you have special requirements or wishes, please let us know.


With kind regards

Ewa Kostka



Quality Management

Susanne Montag



Company management

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