Compare Product Update and AI Operating Stand

Fictional case data and worked reasoning

KI24 · Tested is R18, still used at a site R17. 19 out of 20 correct results apply to the tested combination.

Test point Purpose or comparison Observation Decision	
Product Tested and explained R18 Clearing the stand of the customer R17	
Technical test at least 20, at least 95%	19 of 20 achieved with R18 criterion
Negative test Minimum 20 10 of 10 Unopened	

Expected result

A release file with version matching, independent CRA-files and confirmed AI performance.

Confirm product limit and actual distance

Evaluate CRA evidence and sample separately

Remedial, robustness and compliance

Counter-test and next decision

Confirm R18 and set the test to 10 correct from 10 cases. The version comparison is now documented. The test remains open because of the too small sample. Then set the robustness proof to unexplained and check the separate status again.

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For your observation, specify a findable document.

Check tested, explained and active combination of product and remote processing. Calculate the sample and evaluate the evidence separately.

Verification identification, legal entity and date of processing and responsible body

Product version, remote control and location of use

Combination tested and described in the declaration

CRA product and process documentation

Accuracy values, sample size and target

Proven robustness and actual delivery

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Refer remedial and post-test to the original test order.

Findings and supporting evidence

Remedy, post-test and decision to amend

Tested follow-up test with date, observation and version documentation

Release of the confirmed combination and resubmission

Release by and on the open order and date