Standard coverage and type level

Fictional case data and worked reasoning

A manufacturer uses a standard for device management for a fictitious Class I product. In the model, the official reference contains a restriction on two criteria of remote processing necessary for the product. Another laboratory report mentions an older version not documented on the audited reference date. Six of the nine relevant criteria are confirmed with reference and actual application. The technical documentation falsely covers all nine as fully covered by the standard. In case no specific real standard set is required.

Test point	Purpose or comparison	Observation	Decision
Requirements 9 Applicable criteria 6 with secured coverage			3 further examine separately
Limitation Applying official scope		2 Criteria excluded	Clearing procedures for these gaps
Issue of the report	Tested standard version confirmed	1 Report mentions old edition	Secure version or portability

Expected result

Evidence per requirement and release status of the appropriate assessment method.

Confirm the official basis and actual edition.

assess coverage and the necessary complementary procedure.

Check the certificate and the actual delivered stand.

Counter-test and next decision

Replace the date for the three open positions in the dossier with a new reference date without changing the official location or actual laboratory report, which will not allow the range to be established.

Standard coverage and type level

For your observation, specify a findable document.

Track standard reference, actual application, procedural gap and confirmed scope of the type.

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

Product group, version and time of test

Official reference, restrictions and full scope

Confirmed application per criterion

Type change and required procedural documentation

Location for test report, certification and production

Standard coverage and type level

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

Findings and supporting evidence

Open standard position or lack of evaluation

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

Assessment and release level per product version

Release by and on the open order and date