Method of conformity and release documents

Fictional case data and worked reasoning

KI12 · When learning evaluation is done, the internal way is proven and registration is outdated. In the protection module, the required sectoral assessment evidence is missing.

Test point Purpose or comparison Observation Decision		
Learning evaluation Annex III, No 3, internal control	Registration belongs to 2.5 Locks	
Protection module Sectoral evaluation for 3.2 Internal rating only Blocked		
Counter-probe AI requirements in the report	Only general QMS statements	Locked

Expected result

A market access decision with associated procedures, evidence of conformity and, where appropriate, appropriate registration.

Confirm high risk path and relevant procedure

Match declaration, identification and register reference

Documenting the market step and the stop

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For your observation, specify a findable document.

Determine the audit trail from the confirmed classification and relevant procedural rules. Check the documentation at the actual provision.

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

Purpose and system status

Annex position and relevant product regulation

Procedure decision and, where appropriate, notified body

Declaration and marking of the delivery version

Registration status and actual evidence

Method of conformity and release documents

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

Findings and supporting evidence

Correction order and scope of the new documents

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

Reasoned decision on market step

Release by and on the open order and date