Scope of procedure and release with module H

Fictional case data and worked reasoning

A manufacturer develops a hypervisor delivered independently. The core function and the technical description result in an important product of class II in the case of instruction. He selects module H. The valid scope of the notified body and the confirmation for the previous development and release site are documented. In future, a second location will be responsible for the approval. The internal samples exist. The manufacturer has communicated to the body the intended change of the approved quality system. A documented decision by the body whether the modified system must be met or re-evaluated is missing. Otherwise the previous workflows will remain.

Test point	Purpose or comparison	Observation	Decision
Product category	**Reasoned Class II**	**Core function and category confirmed**	Documenting the Authorized Way
Number of places	**module and product recorded**	**Official entry confirmed**	The job is available
Amended quality system	Decision on enlargement intelligible	Internal samples pass, decision is missing	Reset new location

Expected result

Procedural file with documented scope of proceedings per location and concrete clearance decision.

Assign product core function, category and evaluation method.

Comparing the level of notification, approved system and amendment

Document the extent of release and job decision.

Counter-test and next decision

Take a general audit certificate from the second location into the file. Check whether the change of the approved system and the relevant module H scope have been decided. The open delivery route remains open without this reference.

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For your observation, specify a findable document.

Connect product category, notified body, confirmed quality system and decision to change.

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

Product core function and socket

Selected procedure and official reference

Body, identification number and scope of activity

Authorised location and quality system

Amendment, Communication and Answer

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

Findings and supporting evidence

Test certificates for the observed system effect

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

Delivered scope of delivery and jurisdiction

Release by and on the open order and date