AI prepares · Assessor checks

A completeness record for the assessor

A medical device's technical file checked against your document checklist, with missing or hard-to-find evidence shown. Assessors confirm readiness for detailed review.

Materials	Illustrative sample: a medical device's technical file, the applicable checklist and document versions.
Rule	**A test report for every claimed standard**
Stage	Before detailed assessment

01 Checklist item	02 Document in the file	03 Status
Device description and specification	Technical file, section 1	Located
Risk management file (ISO 14971)	Risk management report, version 3	Located
Test report IEC 60601-1 XLSX Document checklist · row 14 The example on the page · detail on page 2	No matching record	Missing · Confirmed by your assessor
Clinical evaluation report	Clinical evaluation report, no version date	Version to check
Labelling and instructions for use	Instructions for use, draft 2	Located

SOURCE EXCERPTS · THE FINDING IN ROW 3

XLSX Document checklist · row 14

"Required: test report demonstrating conformity with IEC 60601-1, issued by an accredited laboratory."

PDF Test report IEC 60601-1

No document in the submitted file matches this checklist item.

WHY IT MATTERS

Detailed assessment needs a complete file. Found at intake, the missing report is one request to the applicant instead of a stop halfway through the assessor's review.

WHAT THE ASSESSOR DECIDES

Whether the report is required, whether another supplied document covers it, and what to request before detailed assessment.

CONFORMITY DECISIONS STAY WITH YOUR ASSESSORS

A complete technical file is not a conformity decision. Your assessors judge whether the evidence is adequate and raise any nonconformity.

- [ ] Is the report required?
- [ ] Does another document in the file cover it?
- [ ] Gap confirmed by the assessor