

DESIGN FOR USABILITY.

BUILD EVIDENCE FOR COMPLIANCE.

End-to-end IEC 62366-1 & MDR usability engineering and UOUP compliance.

Make usability a foundation for identifying, reducing and controlling use-related risks, supported by robust evidence and regulatory confidence.

YOUR CHALLENGES



USABILITY REQUIREMENTS Which IEC 62366-1 expectations under EU MDR 2017/745 actually apply to your devices?



USE-RELATED RISK How to identify and control use-related risks through robust usability engineering and ISO 14971 risk management?



NOTIFIED BODY & UOUP SCRUTINY How to build defensible User Interface of Unknown Provenance (UOUP) files that withstand Notified Body review?

OUR APPROACH

01 ASSESS

- Comprehensive review of device user interface and existing usability data
- Evaluation of use scenarios, user interactions and potential use errors
- Prioritized usability strategy and action plan



02 IMPLEMENT

- Formative and summative usability study protocol drafting
- End-to-end authoring of compliant usability engineering files and UOUP dossiers
- Seamless integration of usability outputs into risk management documentation



03 ASSURE

- Targeted team training on human factors and usability engineering standards
- On-demand technical expert hotline for user interface queries
- Full support during technical documentation review and Notified Body audits

YOUR BENEFITS



ROBUST USABILITY COMPLIANCE

A structured IEC 62366-1 approach with clear, traceable evidence throughout the usability engineering lifecycle.



STRONGER USE-RELATED RISK CONTROL

Usability engineering integrated with ISO 14971:2019 to identify, evaluate and control foreseeable use errors.



TRACEABLE UOUP EVIDENCE

Well-structured legacy device documentation and usability evidence designed to withstand Notified Body scrutiny.

READY TO STRENGTHEN YOUR USABILITY COMPLIANCE?

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