

Checklist User Needs Review

ISO 13485:2016 Section	Document Section
7.3.2	(A1)

Classes	IEC 62304:2006 Section	Document Section
A, B, C	5.1.8	(All)

1. Summary

With this checklist we verify the completeness and consistency of User Needs.

Relevant documents:

- User Needs (Doc-ID)

2. Checklist

Checklist Items	Yes	No	Comment
The user needs are complete.			
The user needs address all relevant stakeholders.			
The user needs take all relevant use scenarios of the intended use into account.			
The user needs cover all relevant categories (e.g. technical, regulatory, organizational, market).			
The user needs are not ambiguous, self-contradicting or conflicting with each other.			
The user needs are traceable.			
The user needs are testable (if required).			

3. Comments

<Insert comments if applicable>

4. Result

- User needs passed
- User needs not passed
- User needs passed with the following obligations: <Insert if applicable>

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