# Checklist User Needs Review

| ISO 13485:2016 Section | Document Section |
| --- | --- |
| 7.3.2 | (Al) |

| 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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