User Needs List

This is a list of your user needs (also referred to as "stakeholder requirements"). This is what you would most commonly start with for your requirements mapping: it is the most high-level part of your design input. Describe the generic requirements your device will need to meet. Only in a next step, these user needs will be translated into (and linked to) software requirements which will present the technical specifications of your product.

Of course, you could also use your own tool like Jira or GitHub issues for this. Just ensure that the content (i.e. the columns shown here) is roughly the same.

Mapping of Standard Requirements to Document Sections

ISO 13485:2016 Section	Document Section
7.2.1	(All)
7.3.3	(All)

IEC 62366-1:2015 Section	Title	Document Section
5.2	Identify user interface characteristics related to safety and potential use errors	1
5.6	Establish user interface specification	1

1. User Needs

Your user needs should typically take into account:

- Regulatory requirements
- Use requirements for product functionalities, safety and performance in order to fulfill its intended use.
- Requirements from risk management: include all hazard-related use scenarios that must be tested during usability tests (note the last column on the right for that).

User Need ID	User Group	Requirement Description	Safety-Critical?
1	User	The software returns a score predicting Covid contraction based on (. . .).	Yes

User Need ID	User Group	Requirement Description	Safety-Critical?
2	User	Users can read the instructions for use or contact support in case of questions.	Yes
3	Company	The software can be integrated with most laboratory systems in the intended use environment.	No
4	Regulatory authorities	The device is developed in compliance with applicable regulations, norms and standards (e.g. IVDR / MDR, GDPR, HIPAA).	No
5	(...)	(...)	(...)
