

Product Release

After passing the validation phase, the first product can be released to the field. Together with the software product, a release note and user manual will be distributed (either on paper or digitally made available, e.g. via internet or included in the software product itself). The release notes document all features released and all known bugs. The user manual contains the contact details of the manufacturer including support contact, intended use, clinical claims, contra indications, safety warnings, messages, description of the software product, operational security for use, known technical issues, limitations, installation procedure, start-up- operating and shutdown instructions, disposition instructions, technical description. For more details, see ISO82304.