Johner Institute

Implement design changes in compliance with the law*

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Changes to the medical device
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Changes to the intended use? — Yes →
Limitation of the Intended use?
— No ↓
e.g. limitation of indication or patient population, additional contraindication

— Yes →
Extension or change of the intended use? — Yes
— No ↓
e.g. new indication

New intended users or user groups? — Yes
— No ↓
e.g. restriction contraindication, lay users instead of "professionals".

— No →
Change in the clinical application? — Yes
e.g. new anatomical location, different way of application of the product

— No ↓

Change as part of a corrective action? — Yes
(Requires approval by competent authority)
— No ↓

Change in the development or performance specification? — Yes →
Change needs more clinical or usability data to prove GSLA? — Yes
— No ↓
Comparison MEDDEV 2.7/1 Revision 4 e.g. new "Use Scenario

Do new risks require action or are old risks increased? — Yes
— No ↓
e.g. new or higher risks due to changed component

— No →
Change of internal protection measures, energy sources or alarms? — Yes
e.g. change to a two-channel system architecture

— No ↓

Software changes? →
New or major changes to operating system or SOUP? — Yes
— No ↓
e.g. replacement of Tensorflow by Kerra's update from Windows 7 to Windows 10

New or changed architecture or change of an algorithm? — Yes
— No ↓
e.g. other programming language, new top-level components, new tables

Required user entry replaced by a closed-loop algorithm? — Yes
— No ↓
e.g. with defibrillator, which now detects and triggers heartbeat itself

New diagnostic or therapeutic feature, new "interoperability channel"? — Yes
— No ↓
e.g. Ethernet interface added, SW now segments organs independently

New user interface or new representation of data? — Yes
— No ↓
e.g. new screen (in safety-related use scenario?), display as histogram

— No →
— Yes →
Small change? — No
e.g. small change to UI, refactoring of a method, new date on report

— No ↓

Changes to materials? →
Change to materials of human or animal origin? — Yes
— No ↓
e.g. new materials, new concentrations or other preparation of these materials

Changes to materials that contain or affect drugs? — Yes
— No ↓
e.g. new active substances, new concentrations, other application of these materials

— Yes →
Changed materials from existing(!) supplier within specifications?
— No ↓
e.g. replacement of the plastic of a cover with an equivalent

Decision based on the questions on "Change of development or Performance specification?" — Yes ←
Changed materials from new(!) supplier within the specifications? — No
— No ↓

Changes to final sterilization or packaging affecting it? — Yes →
Change of the final sterilization procedure? — Yes
— No ↓
e.g. change from non-sterile to sterile Delivery, ETO instead of steam sterilization

Change to the design that affects the sterilization? — Yes
— No ↓
e.g. new cavities, in which germs can be can deposit, see corresponding standards

Change in packaging that could affect sterility? — Yes
— No ↓
e.g. new blister packs that could wear out the sterile inner packaging

— Yes ←
Change of the shelf life, which is approved by the notified body? — No

— No ↓

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Non-
significant
Change
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Significant
Change
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