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Medical Devices; Quality System Regulation Amendments, 21 CFR Parts 4 and 820 and ISO 13485,

Dear Madame or Sir,

As member of the ISO/TC 121 / SC3 group (DIN), Hamilton Medical thanks for the opportunity to comment on the published document.

We refer to the passus §820.10(d) for life-supporting devices to comply with the requirements in Traceability. We argue that the postulated traceability is not purposeful and necessary, since it adds a huge documentation bearing the risk of unmanageable workload. In addition, there is already an established process which covers all the intended effects in this context.

Mechanical ventilators must be regarded as life-supporting or -sustaining devices, and they are constructed out of hundreds of parts – namely, they are monitored and controlled by a special software, which also has to comply to high standard requirements. But next to built-in software, every part of a ventilator is evaluated in terms of its risk to fail and endanger a patient. This is required e.g. by IEC 60601-1 and related standards.

A critical incident with such a medical device requires a report to the authorities, a response by the manufacturer containing the failure evaluation and the analysis of contributing parts. By European law, manufacturers are furthermore required to trend and document all incidents and report this trend analysis to the authorities (Article 88, Regulation (EU) 2017/745). To our estimation this process already covers the above quoted passus in a very efficient way, therefore we conclude that an additional Traceability does not bring further advantage.

We would suggest that for non-implantable devices, the process of trend reporting as described in the European regulation is sufficient and taken over in the FDA regulations instead of the traceability for all parts.

With kind regards

Hamilton Medical AG

Matthias Himmelstoss