COCIR feedback

Proposal for a Regulation on machinery products

Introduction

The European Commission has asked for feedback to the proposal for a Machinery Regulation[1], to replace the current Machinery Directive. In general, the current Machinery Directive is still fit for purpose, also in view of technological progress and digitisation. The Directive defines the essential health and safety requirements that machinery needs to meet to be placed on the market, but manufacturers are free to use any specific technologies reflecting the State of the Art. Therefore, manufacturers have the possibility to use any technological developments and innovation.

Applicability of the Machinery Regulation to Medical Devices

We appreciate that the proposed Regulation maintains the current principle, "Where, for a certain machinery product, the risks addressed by the essential health and safety requirements set out in Annex III are wholly or partly covered by other more specific Union harmonisation legislation, this Regulation shall not apply to that machinery product to the extent that that specific Union legislation covers such risks." (Article 8).

In addition, the Medical Devices Regulation state, "devices that are also machinery … shall, where a hazard relevant under that Directive exists, also meet the essential health and safety requirements set out in Annex I in that Directive to the extent to which those requirements are more specific than the general safety and performance requirements set out in Chapter II of Annex I to this Regulation".

Furthermore, the current guide for the application of the Machinery Directive states, "all the other obligations relating to the placing on the market of such devices, including the conformity assessment procedure and the risk assessment, are set by the MDD only". COCIR has provided guidance[2] to our members on the applicability of the Essential Health and Safety Requirements of the Machinery Directive (2006/42/EC) to Medical Devices which will have to be updated once the Machinery Regulation will be adopted.

Recommendation: this relationship between the two legislative frameworks needs to be preserved to avoid any unnecessary administrative burden for medical device manufacturers. Concretely, we support maintaining Article 8 of the Commission proposal, and any future guidance needs to include specific reference to the Medical Devices Regulation.

Detailed feedback to Essential Health and Safety Requirements (EHSR)

Overall, the changes in requirements are proportionate and will not have an impact on medical devices, as they are already covered by more specific requirements in the Medical Device Regulation and medical device standards. During our first analysis, we realised that the following requirements need further review:

EHSR 1.1.2 (e) *"A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions, and the machinery product shall be supplied with all the special equipment and accessories, and where appropriate, with the*

[1] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/2019-Machinery-Directive-revision_en
[2] https://www.cocir.org/media-centre/position-papers/article/cocir-recommendation-applicability-of-ehsr-of-the-machinery-directive-2006-42-ec-to-medical-devices.html

description of specific functional test procedures, essential to enable it to be tested, adjusted, maintained and used safely."

Recommendation: The words "safety functions" are too broad and generic to be directly applied to medical devices. Indeed, since the purpose of a medical devices is the diagnosis or treatment of an injury or of a disease, most of the functions of a medical device could be considered as impacting the safety of the operator or of the patient. The scope of this EHSR coming from the machinery directive should be limited to the safety functions ensuring the safety of the operator. This should be clarified either in the Machinery Regulation or in a guideline for the application of EHSR on medical devices.

We propose to change the requirement to "A machinery product shall be designed and constructed in such a way that it is possible for the user to test the safety functions ensuring the safety of the operator…."

Article 1.2.1 (f) *"the tracing log of the data generated in relation to an intervention and of the versions of safety software uploaded after the machinery product has been placed on the market or put into service, is enabled for five years after such upload, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority;"*

Recommendation: Under MDR, a safety related change on the software triggers a new UDI-DI which will be recorded in service records, in the Technical File, and in EUDAMED. It should be clarified that this EHSR does not introduce new requirements for medical devices.

Article 1.2.1 (g) *"recording of data on the safety related decision-making process after the machinery product has been placed on the market or put into service, is enabled and that such data is retained for one year after its collection, exclusively to demonstrate the conformity of the machinery product with this Annex further to a reasoned request from a competent national authority."*

Recommendation: It should be further clarified when such a requirement is applicable. In our view, there are currently no use cases in the medical device that would require such recording.