

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on Medical Devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential

Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this standard.