

Examination of Interpretation document on relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (Active implantable) (*sic*) medical devices and Directive 2006/42/EC on machinery

Haroon Atchia

Interpretation of the relation between the revised Directives 90/385/EEC and 93/42/EEC concerning (Active implantable) (*sic*) medical devices and Directive 2006/42/EC on machinery.

§(5) of the Interpretation document clarifies that Directive 2006/42/EC does not apply providing that certain EHSR of the Directive become part of the two Directives on medical devices. It does not mean that the ERs of Council Directive 90/385/EEC and 93/42/EEC as amended by Amending Directive 2007/47/EC already integrate applicable EHSR of Council Directive 2006/47/EC, contrary to practice being seen to date or as communicated by some Notified Bodies.

The Interpretative document, rather, reiterates the following which are naturally logical (§16) of the Interpretative document of the Commission's Services):

- ✚ Conformity Assessment for a dual medical device – machinery may be combined
- ✚ Conformity Assessment for a dual medical device – machinery can be according to the applicable medical device Directive <which is illogical>

The second interpretation in §(6) of the Interpretative document of the Commission's Services cannot be sustained, inasmuch that Essential Requirements do not constitute analysis of risk (unless of course the intention was direction to Safety Principles espoused by Essential Requirement 2 Council Directive 93/42/EEC for instance).

§(7) of the interpretation document alludes to the need for revision of Harmonised Standards applicable to medical devices but would now need to encompass machinery too. It is unknown how this is being attended by the Commission.

An illustration of dual medical device-machinery EHSR application is given in §(8), specifically errors arising from fitting or re-fitting certain parts.

Although the illustration is not a good one for the purposes of clarifying such duality, the following may serve as elaboration (Figure 1).

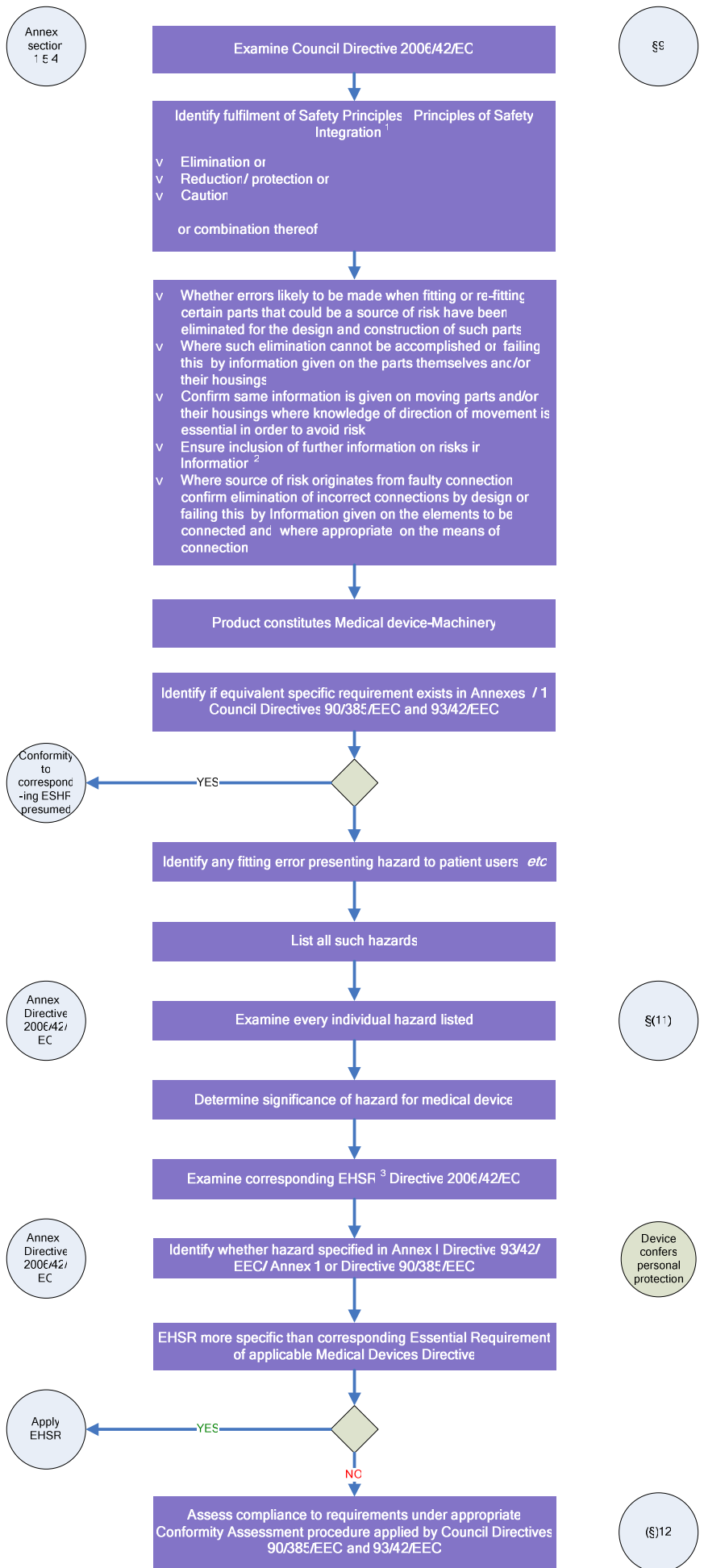


Figure 1 Flow chart condensing interpretation

By this token therefore, §(5) cannot apply because of nonsense and §(6) second interpretation requires re-consideration.

Bibliography

1. Interpretative document of the Commission's Services [ENTR/F/3/FBE/pdw D (2009) 27250 (21 August 2009).
2. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) L157/24 *Official Journal of the European Union* 9 June 2006.

¹ = As espoused by Essential Requirement 2 Council Directives 90/385/EEC | 93/42/EEC and Essential Health and Safety Requirement 1.1.2(b) Council Directive 2006/42/EC, respectively

² = (Information to be supplied with product) Formal written statement communicating facts about a given product essential to its safe and proper use and other required instruction and elements as required by regulation

³ = Essential Health and Safety Requirement, Council Directive 2006/42/EC