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

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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).

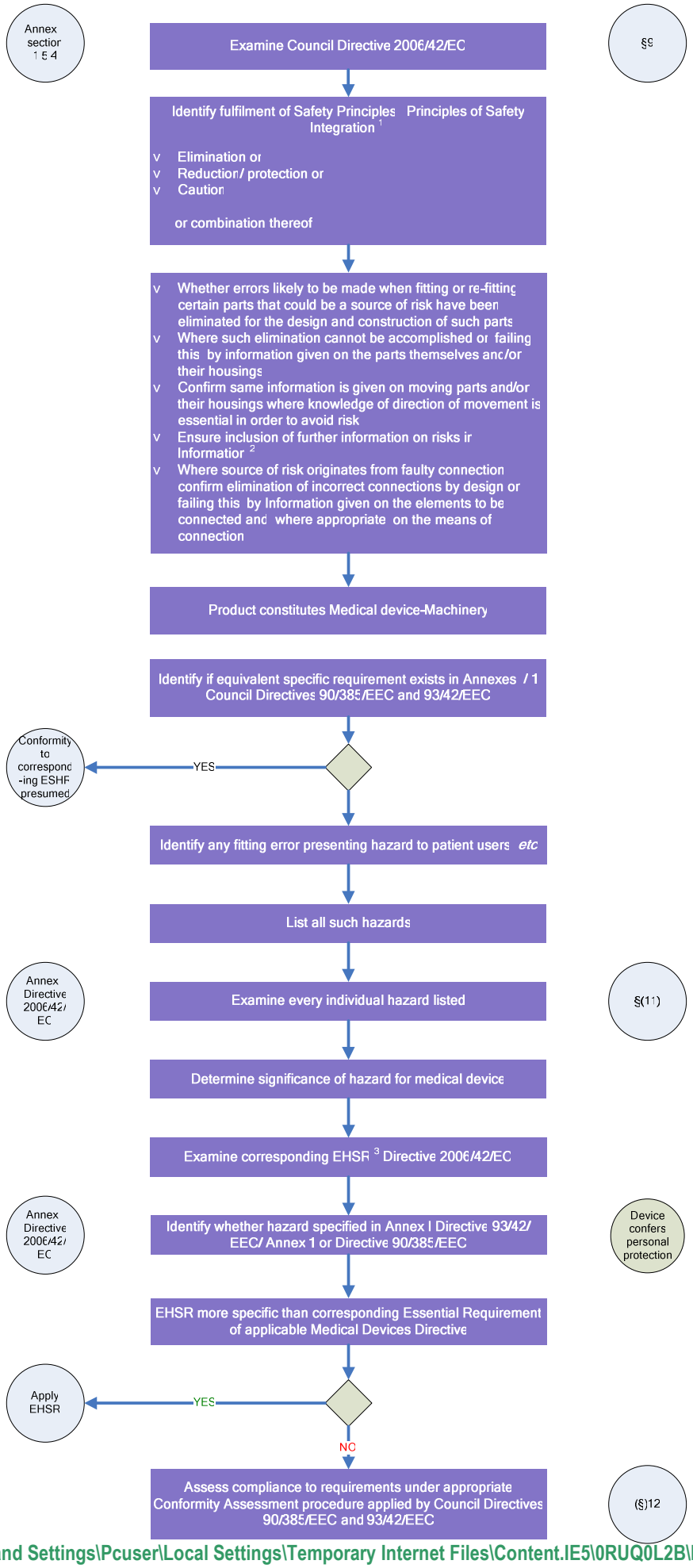
Annex section 1 5 4
Examine Council Directive 2006/42/EC
§9
Identify fulfilment of Safety Principles Principles of Safety Integration [1]
v Elimination or
v Reduction/ protection or
v Caution
or combination thereof
v Whether errors likely to be made when fitting or re-fitting certain parts that could be a source of risk have been eliminated for the design and construction of such parts
v Where such elimination cannot be accomplished or failing this by information given on the parts themselves and/or their housings
v Confirm same information is given on moving parts and/or their housings where knowledge of direction of movement is essential in order to avoid risk
v Ensure inclusion of further information on risks in Information [2]
v Where source of risk originates from faulty connection confirm elimination of incorrect connections by design or failing this by Information given on the elements to be connected and where appropriate on the means of connection
Product constitutes Medical device-Machinery
Identify if equivalent specific requirement exists in Annexes / 1 Council Directives 90/385/EEC and 93/42/EEC
Conformity to corresponding ESHR presumed
YES
Identify any fitting error presenting hazard to patient users etc
List all such hazards
Annex Directive 2006/42/EC
Examine every individual hazard listed
§(11)
Determine significance of hazard for medical device
Examine corresponding EHSR [3] Directive 2006/42/EC
Annex Directive 2006/42/EC
Identify whether hazard specified in Annex I Directive 93/42/EEC/ Annex 1 or Directive 90/385/EEC
Device confers personal protection
EHSR more specific than corresponding Essential Requirement of applicable Medical Devices Directive
Apply EHSR
YES
NO
Assess compliance to requirements under appropriate Conformity Assessment procedure applied by Council Directives 90/385/EEC and 93/42/EEC
(§)12

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