Examination of Interpretation document on relation between the revised Directive 93/42/EEC concerning medical devices and Directive 90/686/EEC on personal protective equipment

Interpretative document of the Commission's Services

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Interpretation of the relation between the revised Directive 93/42/EEC concerning medical devices and Directive 90/686/EEC on personal protective equipment [ENTR/F/3/PBE/pdw D (2009) 27251 (21 August 2009)] reiterates similar premiss concerning dual application of Essential Requirements for medical devices and Basic Health and Safety Requirements for personal protective equipment for products where dual intended purpose is declared by the Manufacturer.

Although offering clearer interpretation than does Interpretative document ENTR/F/3/PBE/pdw D (2009) 27250 on machinery, this document is riddled with incorrect terms (*eg*, pharmaceuticals authority) and some absent from or contrary to the Directives or whose meaning is un-defined or grammatically incorrect (*eg*, double purpose, principal intended purpose, *etc*), incorrect English spelling is used (US).

§(6) confusingly states that the provision of Article 2(1)f Council Directive 2007/47/EC is unclear concerning control to be exercised, specifically the BSHR of the PPE Directive. Close examination of the wording of the Articles, however, rebuts this:

> 2. For the purposes of this Directive, PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.
>
> PPE shall also cover:
>
> (a) a unit constituted by several devices or appliances which have been integrally combined by the manufacturer for the protection of an individual against one or more potentially simultaneous risks;
> (b) a protective device or appliance combined, separably or inseparably, with personal non-protective equipment worn or held by an individual for the execution of a specific activity;
> (c) interchangeable PPE components which are essential to its satisfactory functioning and used exclusively for such equipment.

3. Any system placed on the market in conjunction with PPE for its connection to another external, additional device shall be regarded as an integral part of that equipment even if the system is not intended to be worn or held permanently by the user for the entire period of risk exposure.

Article 1 Council Directive 89/686/EEC (as Amended)

Further,

The PPE referred to in Article 1 must satisfy the basic health and safety requirements laid down in Annex II.

Article 3 Council Directive 89/686/EEC (as Amended)

As with the Machinery Directive, a dual medical device – PPE must undergo (respective) Conformity Assessment according to both Directives. It would seem absurd that the Manufacturer should be permitted or encouraged to decide what requirements apply, rather the correct argument must be to apply both legal tests fully then conclude the extent to which Conformity Assessment elements could be consolidated or combined. Indeed, as mentioned in §(10) (Verification of the Compliance with the relevant essential requirements), in case of simultaneous application of two or more Directives the product must undergo Conformity Assessment according to all applicable Directives unless otherwise provided (in a particular Directive or other legal instrument).

The sense of §(11) appears incorrect and should be tested legally, inasmuch arguing that Conformity Assessment of a product with principally medical device (intended purpose) and ancillary PPE functions should be full for the medical device and partial for the PPE element (*ie*, restricted to BSHR). This cannot surely be correct given preceding arguments plus the fact that Conformity Assessment extends beyond the (Basic Health and Safety) Essential Requirements combined or singly.

The impression that the two Interpretative documents are deliberately obfuscatory and hasty is hard to dismiss:

Logically, either one Directive is supererogatory or superial over another or it is not therefore in the case of the latter both apply equally and fully while in the case of the former, the so-called principal intended purpose would create an analogous situation such as exists and is provided by, for instance Article 2 Amending Directive 2007/47/EC amending Article 1.3 paragraph 2 Council

Directive 93/42/EEC concerning a medical device containing a medicinal substance exerting ancillary action.

Once anticipates the publication of the next Interpretative document which would obviously cover a medical device that is also a machinery and PPE!

Refer to flowchart condensing the Interpretations.

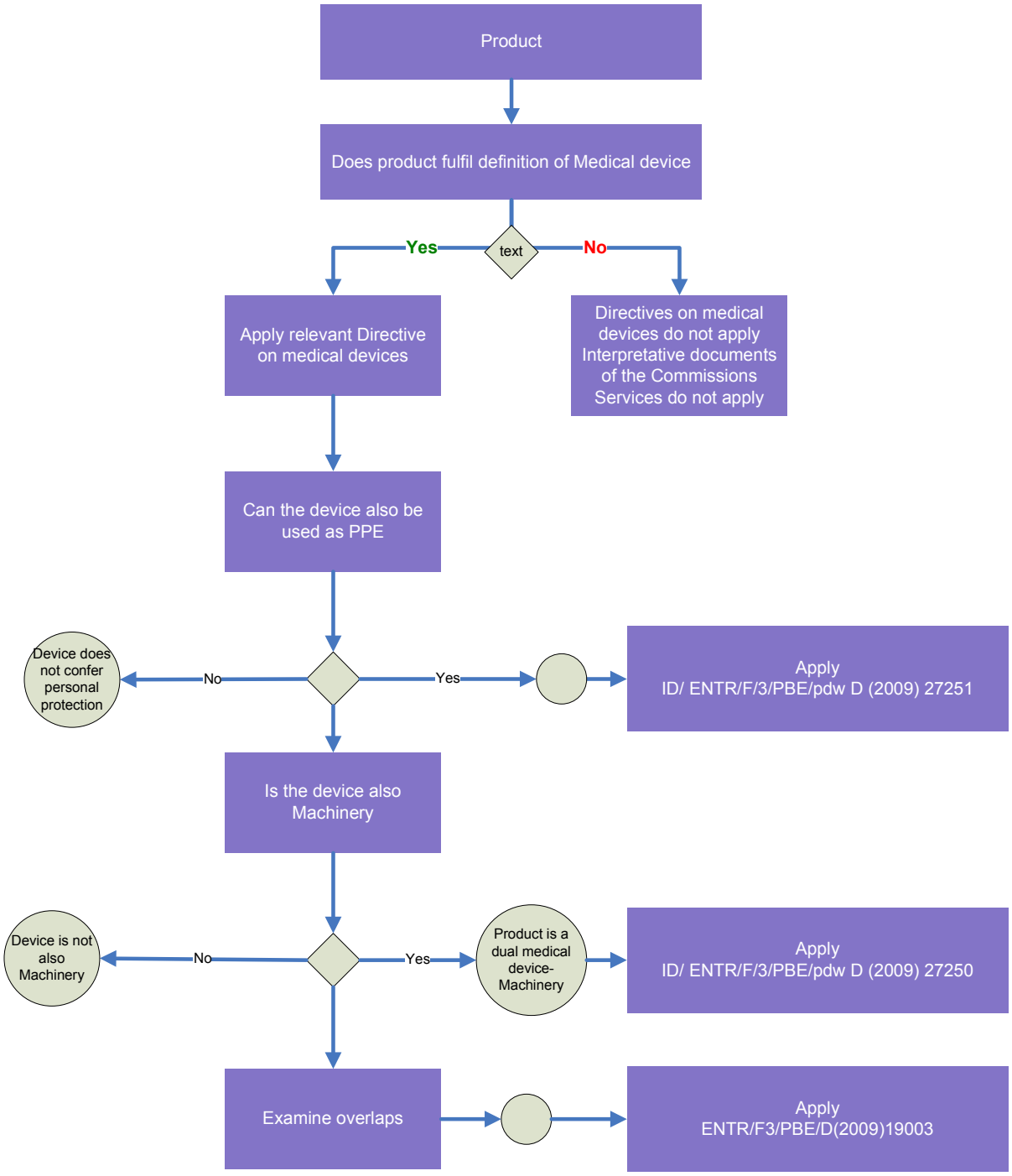

Figure 1 Flowchart condensing the Interpretations

Bibliography

1. Interpretative document of the Commission's Services [ENTR/F/3/FBE/pdw D (2009) 27250 (21 August 2009).
2. Interpretation of the relation between the revised Directive 93/42/EEC concerning medical devices and Directive 90/686/EEC on personal protective equipment [ENTR/F/3/PBE/pdw D (2009) 27251 (21 August 2009)]