Overview of relationship between GPSD and certain sector directives

(Where no sector provisions are indicated in the table the GPSD provision applies)

GPSD	Medical Devices[1]	Construction Products	Machinery	Medicinal Products	Motor Vehicles
Article 3.1 – Obligation for producer to place only safe products on the market	IVDD: Articles 2 and 3, Annex MDD: Articles 2 and 3, Annex AIMDD: Articles 2 and 3, Annex	Articles 2 and 3, ref. Annex I, §1 to §5	Article 3, ref. Annex I, in particular paragraph 1.1.2.a)	Article 6, ref. articles 8, 9, 10, but not all risks. [to be discussed]	Articles 3 and 4 re. Annexes III, IV and XI, 'technical requirements of relevant separate Directives in Annexes IV and XI' (but just in relation to authorisation system) Article 6 (Certificate of Conformity) Article 7.3
Article 5.1, subparagraph 1 – Obligation for producer to inform consumers on risks	IVDD: Article 3, ref. Annex I, Section 8 MDD: Article 3, ref. Annex I, Section 13 AIMDD: Article 3, ref. Annex I, Section 15	NO PROVISION	Article 3, ref. Annex I, 1.7.2, 1.7.3 and 1.7.4	Articles 54 (f), (g), (i) and (n), 58, 59 (c), (d) and (e), 63.2, 66, 67, 68 and 69.1	Article 6.4
Article 5.1, subparagraph 3 and 4 – identification of producer	IVDD: Article 3, ref. Annex I, Section 8 MDD: Article 3, ref. Annex I, Section 13 AIMDD: Article 3, ref. Annex I, Section 12	Article 13, ref. Annex III, § 4.1, fifth indent, but only where technical specifications have been developed	Annex I, point 1 of the preliminary observations, last paragraph, ref. 1.7.3	Articles 54 (k), 58, 59.1(a), fifth dash, 66.3, fourth dash, 67, 69.1, second dash	Articles 6.1 and 6.3
Article 5.1, subparagraph 3	IVDD: Article 3, ref. Annex I, Section 8	Article 13, ref. Annex III, § 4.1, fifth indent, but only	Annex I, point 1 of the preliminary observations, last	Articles 54 (a) to (d), (l) and (m), 58, 59.1(a), first to fourth	Articles 6.1 (certificate of conformity), 6.3 and 6.4

[1] There are three main Directives in the regulatory framework for medical devices which are: Council Directive 90/385/EEC of 20 June on the approximation of the laws of the Member States relating to active implantable medical devices, 20.07.1990, OJ L 189/17 (referred to as AIMDD), Council Directive 93/42/EEC on medical devices of 14 June 1993, 12.07.1993, OJ L 169/1 (referred to as MDD) and Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (referred to as IVDD)

GPSD	Medical Devices[1]	Construction Products	Machinery	Medicinal Products	Motor Vehicles
and 4 – identification of product	MDD: Article 3, ref. Annex I, Section 13 AIMDD: Article 3, ref. Annex I, Section 12	where technical specifications have been developed	paragraph, ref. 1.7.3	dashes, 66.3, first, second and fifth dashes, 67, 69.1, first, fifth and sixth dashes	
Articles 5.1, subparagraph 3, 4 and 5 – Obligation for producers to follow-up product safety after the placing on the market of their products	IVDD: Article 9, ref Annex III, § 5 ; Annex IV, § 3.1 ; Annex VI, § 3 ; Annex VII, § 3.1. MDD: Article 11 (Conformity assessment procedures), ref. Annex II, § 3.1 seventh dash and § 3.2.e); Annex IV, § 3; Annex V, § 3.1 eighth dash and § 3.2.d); Annex VI, § 3.1 eighth dash; Annex VII, § 4 except for custom made medical devices and devices for clinical investigation AIMDD: Article 9, ref Annex II, § 3.1; Annex IV, § 3.	NO PROVISION [only factory control foreseen in Annex III.2]	NO PROVISION	Article 98.2 (re. advertising) Articles 103 and 104	NO PROVISION
Article 5.3 – Obligation for producers to inform the authorities of dangerous products and action taken to prevent risk	IVDD: Article 9, ref Annex III, § 5; Annex IV, § 3.1; Annex VI, § 3; Annex VII, § 3.1. except for in medical devices for performance evaluation. MDD: Article 11 (Conformity assessment procedures), ref. Annex II, § 3.1 seventh dash, last paragraph, (i) & (ii); Annex IV, § 3 (i) & (ii); Annex V, § 3.1 eighth dash, (i) & (ii); Annex VI, § 3.1 eighth dash, (i) & (ii); Annex VII, § 4 (i) & (ii); Article 10 ref. Annex X § 2.3.5 (for clinical evaluation MD) except for custom made medical devices and devices for clinical investigation AIMDD: Article 9, ref Annex II, § 3.1; Annex IV, § 3.	NO PROVISION	NO PROVISION	Article 104	NO PROVISION

GPSD	Medical Devices[1]	Construction Products	Machinery	Medicinal Products	Motor Vehicles
	Article 10 (for clinical evalution) Annex X, § 2.3.5. Adverse events must be recorded, but it does not say how or if they should be notified.				
Article 5.4 – Obligation for producers to cooperate with the competent authorities on action to prevent risks	NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions applicable to medical devices.	NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions applicable to construction products.	NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions applicable to machinery.	Article 98.2 re. monitoring of advertising Articles 103 and 104	NO PROVISION. Co-operation in line with this article undertaken by sector authorities in view of the provisions applicable to motor vehicles.
Article 5 – Obligation for *distributor* not to supply dangerous product, to participate in safety monitoring of products and in tracing dangerous products etc	NO PROVISION	NO PROVISION	NO PROVISION. However, the general provision in Article 2(1) that only safe products may be placed on the market has implications for whoever places them on the market. In practice MS authorities address distributors as well as manufacturers in case of non-conforming products. See also Art. 8(7).	Articles 76, 77 and 79 Article 80 (a), (d), (e) and (f) (*wholesalers*) Article 81 and 82 second paragraph (*pharmacists*)	NO PROVISION
Article 6, subparagraphs 1 and 2 – Obligation on the Member States to establish or nominate authorities competent for enforcement	NO PROVISION; it is implied in the Directives that such authority is established or nominated	Annex IV, last paragraph	Annex VII, point 7 This is an implicit obligation in order for the MS to fulfil their enforcement obligations under the Directive. MS implementation texts give such information. Note that an equivalent obligation to that laid down in Article 6, subparagraphs 1 and 2, of the GPSD has been introduced in the proposal for the revised Directive.	Article 6.1	Article 3.1 ref Article 2, twelfth dash ('approval authority')

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Article 7 – Obligation on the Member States to adopt rules on penalties and to follow up these rules	NO PROVISION	NO PROVISION	NO PROVISION. However, note that an equivalent provision to Article 7 of the GPSD has been introduced in the proposal for the revised Directive.	Article 99	NO PROVISION
Article 8.1. (a) – power to make checks, take samples	NO PROVISION	NO PROVISION	NO PROVISION. However, such powers fall within the normal scope of enforcement.	Article 19 Article 61 (packaging and leaflet) Article 77.5 (for wholesalers) Articles 111 to 114 (inspection in general by competent authorities)	Annex X Section 3 (especially 3.5)
Article 8.1 (b) – (c) – power to set conditions for marketing	IVDD: Article 8, article 13, article 17 MDD: Article 8.1 (restriction to marketing within the "interim measures"); article 14b ("availability "subjected to particular requirements" within the transitional measures); article 18 (b) AIMDD: Article 7, article 13	NO PROVISION	Article 7, paragraph 1 Article 10.4 (b)	Article 61.2, ref. article 64 (packaging and leaflet)	Articles 4.5 and 4.6 Article 7.1 and 7.2 Article 11.2
Article 8.1 (d) – (f) – power to ban or recall	IVDD: Article 8, article 13, article 17 MDD: Article 8 (safeguard clause: 8.1 for interim measures and 8.3 for non-complying devices); article 14b (transitional measures) & article 18 (wrongly affixed CE marking) AIMDD: Article 7, article 13	Articles 15 and 21.1, but not for recall	Article 7, paragraph 1 Article 10.4 (b)	Article 64 (for manufacturing); Article 77.6 (for wholesale) Article 88.1 and 88.3 (re. ban in advertising) Article 116 to 118	Article 4.2 (but only in relation to the authorisation system and not for recall) Article 7.3
Art 9 – Market surveillance strategy	NO PROVISION	NO PROVISION	NO PROVISION	Article 97 (re. advertising monitoring) Title IX 'Pharmacovigilance' (articles 101 to 108)	NO PROVISION

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Article 10 – Establishment of procedures for administrative co-operation between competent authorities of the various Member States	NO PROVISION, but procedures established by sector authorities to be continued in practice.	NO PROVISION, but procedures established by sector authorities to be continued in practice.	NO PROVISION, but procedures established by sector authorities to be continued in practice.	Title III, Chapter 4 'Mutual recognition' (articles 27 to 39) Articles 77.4 and 77.7 (information re. wholesale authorisation of medicinal products) Article 105.1 and 105.2 (pharmacovigilance) Article 122 and 124	Articles 4.5 and 4.6 Article 5.4, last phrase in fourth paragraph and 5.5 Article 10 Article 11.5 Article 14
Article 11 – Obligation to notify measures which restrict placing on the market of products	IVDD: Article 8, article 13, article 17 MDD: Article 8, article 14b, article 18 AIMDD: Article 7, article 13	Article 21 [safeguard measures, but limited to products in conformity with directive]	Article 7 [safeguard measures – but limited to CE marked products]	Article 107	Article 4.2 (but only in relation to the authorisation system) Article 7.3 Article 11.2, 11.5 and 11.6 [limited scope]
Article 12 – Obligation to notify under RAPEX measures and other action concerning products posing serious risks	IVDD: Article 11 MDD: Article 10 AIMDD: Article 8	NO PROVISION	NO PROVISION	Article 105.2	NO PROVISION
Article 13 – Powers and procedures for Community rapid intervention measures	NO PROVISION	NO PROVISION	NO PROVISION	Article 32	NO PROVISION
Article 14 and 15 – Committee procedures for rapid intervention	NO PROVISION	NO PROVISION	NO PROVISION	Article 32	NO PROVISION
Article 16 – Provisions on access to information on	IVDD: Article 19 MDD: Article 20, ref Annex XI § 7 AIMDD: Article 15	NO PROVISION	NO PROVISION. Note than an equivalent provision on protection of confidentiality has been introduced in the proposal	Article 19.4	NO PROVISION

GPSD	Medical Devices[1]	Construction Products	Machinery	Medicinal Products	Motor Vehicles
product risks and protection of confidentiality			for the revised Directive.		
Article 17 – relationship with the directive on liability for defective products	NO PROVISION	NO PROVISION	NO PROVISION	NO PROVISION	NO PROVISION
Article 18 – motivation	MDD: Articles 8.1, 14b, 19.1	NO PROVISION**]**	Articles 11 and 7 [only for safeguard measures]. Note than an equivalent provision to Article 18 of the GPSD has been introduced in the proposal for the revised Directive.	Articles 77.7, 125	Articles 4.2 (but only in relation to the authorisation system); 5.3 third paragraph and 5.4, third paragraph (motivation of the 'extension' of the revised approval certificate) Article 7.3 Article 11.5 Article 12