Corrigendum to Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU

(Official Journal of the European Union L 117 of 5 May 2017)

On page 242, the first subparagraph of Article 83(1):

for: '… referred to in Sections 1 and 5 of Annex I and which …',

read: '… referred to in Sections 1 and 8 of Annex I and which …'.

On page 256, Article 110(8):

for: '8. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later, comply with Article 27(3) and Article 28(1) and Article 51(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Decision 2010/227/EU.',

read: '8. By way of derogation from Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies which, during the period starting on the later of the dates referred to in point (f) of Article 113(3) and ending 18 months later, comply with Articles 26(3), 28(1) and 51(5) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC as specified in Decision 2010/227/EU.'.

On page 257, point (b) of the first paragraph of Article 112:

for: '(b) Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, and …',

read: '(b) Article 10, points (a) and (b) of Article 12(1) and Article 15(5) of Directive 98/79/EC, and ...'.

On page 257, Article 113(3), point (a):

for: '(a) Article 27(3) and Article 51(5) shall apply from 27 November 2023;',

read: '(a) Articles 26(3) and 51(5) shall apply from 18 months after the later of the dates referred to in point (f);'.

On page 277, Annex III, Section 1, point (b), fifth bullet point:

for: '— methods and protocols to manage the events subject to the trend report …',

read: '— methods and protocols to manage the incidents subject to the trend report …'.

On page 304, Annex VIII, Section 2.2, introductory phrase:

for: 'Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, …',

read: 'Devices intended to be used for blood grouping, or to determine foeto-maternal blood group incompatibility, or for tissue typing to ensure the immunological compatibility of blood, …'.