

## [<sup>F1</sup>SCHEDULE 2A

### Modification of Annexes to Directives 90/385, 93/42, 98/79

#### Textual Amendments

- F1** Sch. 2A inserted (E.W.S.) (31.12.2020) by [The Medical Devices \(Amendment etc.\) \(EU Exit\) Regulations 2019 \(S.I. 2019/791\)](#), regs. 1(1), **12** (as amended by [S.I. 2020/1478](#), regs. 1(3), Sch. 2 paras. 2, 56, **57**); 2020 c. 1, **Sch. 5 para. 1(1)**

## PART 2

### Modification of Annexes to Directive 93/42

#### 17. In Annex VI—

- (a) omit “EC” each time it occurs including in the title;
- (b) for “the notified body” each time it occurs substitute “the approved body”;
- (c) for “this Directive” each time it occurs substitute “the Regulations”;
- (d) in Section 2—
  - (i) for “CE marking in accordance with Article 17” substitute “UK marking”;
  - (ii) for “CE marking must” substitute “UK marking must”;
- (e) in Section 3.1, for—
  - (i) “a notified body” substitute “an approved body”;
  - (ii) “other notified body” substitute “other approved body”;
- (f) in Section 3.3, for the first sentence substitute—

“The quality system must be audited by the approved body to determine whether it meets the requirements referred to in Section 3.2.”;
- (g) in Section 3.4, for the second paragraph substitute—

“The proposed changes must be assessed by the approved body so as to verify whether the quality system after these changes would still meet the requirements referred to in Section 3.2.”;
- (h) in Section 5.1—
  - (i) for “authorised representative” substitute “UK responsible person”;
  - (ii) for “national authorities” substitute “Secretary of State”;
- (i) in Section 6, in the opening paragraph, for “Article 11(2)” substitute “regulation 13(2) of the Regulations”;
- (j) in Section 6.3, for “competent authority” substitute “Secretary of State”.]

**Status:**

Point in time view as at 31/12/2020.

**Changes to legislation:**

The Medical Devices Regulations 2002, Paragraph 17 is up to date with all changes known to be in force on or before 16 July 2024. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations.