SCHEDULE 3

Regulation 23

Provisions breach of which is an offence under regulation 23

Table 1

Regulation	*Title of the regulation*
5	Reprocessing of single-use devices
6	Requirement on health institutions relating to implanted devices
7	Provision of information relating to custom-made devices
9	Retention of documentation relating to conformity assessments and custom-made devices
10	UK(NI) indication
11	Ethical review of clinical investigations
12(1)	Prior authorisation of clinical investigations by the Secretary of State
14	Damage compensation in relation to clinical investigations
15	Retention of documentation relating to clinical investigations

Table 2

Article	*Title of the article*
5(1) to (3), (5)	Placing on the market and putting into service
6(1)-(3)	Distance sales
7	Claims
9(3), (4)	Common specifications
10 (except in paragraph 14, only the first sub-paragraph)	General obligations on manufacturers
11(1), (3), (6)	Authorised representative
12	Change of authorised representative
13	General obligations of importers
14	General obligations of distributors
15	Person responsible for regulatory compliance
16(3), (4)	Cases in which obligations of manufacturers apply to importers, distributors or other persons.
17(1)	Single-use devices and their reprocessing
18(1)	Implant card and information to be supplied to the patient with an implanted device

Article	*Title of the article*
21(2)	Devices for special purposes
22(1), (3) to (5)	Systems and procedure packs
23(1)	Parts and components
25(1), (2)	Identification within the supply chain
32(1), (2)	Summary of safety and clinical performance
52(1) to (4), (6) to (11), (13)	Conformity assessment procedures
53(3)	Involvement of notified bodies in conformity assessment procedures
58(1)	Voluntary change of notified body
62(1), (2) (only the first sub-paragraph), (3) (only the first sub-paragraph), (4), (5), (7)	General requirements regarding clinical investigations conducted to demonstrate conformity of devices
82(1)	Requirements regarding other clinical investigations
84	Post-market surveillance plan
85	Post-market surveillance report
86	Periodic safety update report
89(1), (3) (only the second sub-paragraph),(5), (8)	Analysis of serious incidents and field safety corrective actions
94 (only the final paragraph)	Evaluation of devices suspected of presenting an unacceptable risk or other non-compliance