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STATUTORY INSTRUMENTS

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**2020 No. 1478**

**EXITING THE EUROPEAN UNION  
CONSUMER PROTECTION**

The Medical Devices (Amendment  
etc.) (EU Exit) Regulations 2020

*Made - - - - 8th December 2020  
Coming into force in accordance with  
regulation 1(2) and (3)*

**THE MEDICAL DEVICES (AMENDMENT  
ETC.) (EU EXIT) REGULATIONS 2020**

1. Citation, commencement and application
  2. Amendment of the Medical Devices Regulations 2002
  3. Amendment of the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
  4. Amendment of the Human Medicines and Medical Devices (Amendment etc.) (EU Exit) Regulations 2019
- Signature

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SCHEDULE 1 — Amendment of the Medical Devices Regulations 2002

1. The Medical Devices Regulations 2002 are amended in accordance with...
2. Amendment of regulation 2
3. Insertion of regulation 10A
4. Amendment of regulation 16
5. Amendment of regulation 17
6. Substitution of regulation 19
7. Insertion of regulation 19B
8. Insertion of regulation 21B
9. Insertion of regulation 24A
10. Amendment of regulation 29
11. Amendment of regulation 30
12. Amendment of regulation 35
13. Insertion of regulation 36A
14. Amendment of regulation 41

*Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.*

15. Substitution of regulation 44
16. Amendment of regulation 45
17. Insertion of regulation 47A
18. Amendment of regulation 48
19. Amendment of regulation 49
20. Amendment of regulation 53
21. Amendment of regulation 55
22. Amendment of regulation 58
23. Amendment of regulation 60
24. Amendment of regulation 61
25. Amendment of regulation 63
26. Amendment of regulation 65

SCHEDULE 2 — Amendment of the Medical Devices (Amendment etc.) (EU Exit)  
Regulations 2019

1. Amendment of the Medical Devices (Amendment etc.) (EU Exit)  
Regulations 2019
2. Amendment of regulation 1
3. Substitution of regulation 3(2)
4. Amendment of regulation 3(3)
5. Amendment of regulation 3(4)
6. Insertion of regulation 3(4A)
7. Amendment of regulation 3(5)
8. Amendment of regulation 3(6)
9. Amendment of regulation 3(7)
10. Omission of regulation 4(2)
11. Amendment of regulation 4(3)
12. Amendment of regulation 4(4)
13. Amendment of regulation 4(6)
14. Insertion of regulation 4(6A)
15. Insertion of regulation 4(6B)
16. Substitution of regulation 4(7)
17. Insertion of regulation 4(7A)
18. Insertion of regulation 4(7B)
19. Insertion of regulation 4(7C)
20. Insertion of regulation 4(7D)
21. Substitution of regulation 4(8)
22. Substitution of regulation 4(9)
23. Insertion of regulation 4(10)
24. Insertion of regulation 4(11)
25. Amendment of regulation 5(3)
26. Insertion of regulation 5(4A)
27. Insertion of regulation 5(4B)
28. Substitution of regulation 5(5)
29. Insertion of regulation 5(5A)
30. Insertion of regulation 5(5B)
31. Insertion of regulation 5(5C)
32. Substitution of regulation 5(6)
33. Substitution of regulation 5(7)
34. Insertion of regulation 5(8)
35. Omission of regulation 6(2)
36. Amendment of regulation 6(3)
37. Substitution of regulation 6(4)

38. Insertion of regulation 6(4A)
39. Insertion of regulation 6(4B)
40. Substitution of regulation 6(5)
41. Insertion of regulation 6(5A)
42. Substitution of regulation 6(6)
43. Substitution of regulation 6(7)
44. Insertion of regulation 6(8)
45. Insertion of regulation 6(9)
46. Insertion of regulation 6(10)
47. Substitution of regulation 7
48. Substitution of regulation 8(2) and (3)
49. Insertion of regulation 8(4A)
50. Amendment of regulation 8(5)
51. Substitution of regulation 9(4)
52. Amendment of regulation 9(5)
53. Insertion of regulation 9(6A)
54. Omission of regulation 10
55. Omission of regulation 11
56. Substitution of Schedule 2A as inserted by regulation 12
57. Omission of Schedules 3 to 28 as inserted by regulation 12

Explanatory Note