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STATUTORY INSTRUMENTS

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**2000 No. 1315**

**CONSUMER PROTECTION**

The In Vitro Diagnostic Medical  
Devices Regulations 2000 (revoked)<sup>F1</sup>

<i>Made</i>	- - - -	<i>11th May 2000</i>
<i>Laid before Parliament</i>		<i>15th May 2000</i>
<i>Coming into force</i>		<i>7th June 2000</i>

**THE IN VITRO DIAGNOSTIC MEDICAL  
DEVICES REGULATIONS 2000 (REVOKED)**

1. Citation and commencement
  2. Interpretation
  3. Scope of the Regulations
  4. Essential requirements for relevant devices
  5. CE marking
  6. CE marking of relevant devices that come within the scope of more than one Directive
  7. Relevant devices not ready for use
  8. Exemptions from regulations 4, 5 and 7
  9. Procedure for affixing a CE marking
  10. Supplemental provisions relating to conformity assessment procedures
  11. CE marking of a product which is not a relevant device
  12. Devices for performance evaluation
  13. Designation of authorised representatives for registration purposes
  14. Registration of manufacturers etc. of devices
  15. Designation etc. of notified bodies
  16. Functions of notified bodies
  17. Fees charged by UK notified bodies
  18. Enforcement etc.
  19. Notice procedures
  20. Transitional provisions
  21. Notification of decisions etc.
  22. Amendments to the 1994 Regulations
  23. Amendments to the 1995 Regulations
- Signature

**Changes to legislation:** There are currently no known outstanding effects for the *The In Vitro Diagnostic Medical Devices Regulations 2000 (revoked)*. (See end of Document for details)

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SCHEDULE 1 — AMENDMENTS TO THE 1994 REGULATIONS

1. In regulation 2(1) of the 1994 Regulations (interpretation)—
2. In regulation 3(2) of the 1994 Regulations (application of the...
3. After regulation 12 of the 1994 Regulations (general provisions relating...
4. In regulation 14 of the 1994 Regulations (registration of persons...
5. In regulation 16 of the 1994 Regulations (clinical investigations)—
6. In regulation 17 of the 1994 Regulations (notified bodies), after...
7. For paragraph (1) of regulation 18 of the 1994 Regulations...
8. (1) In paragraph (3) of regulation 19 of the 1994...
9. After regulation 19 of the 1994 Regulations there shall be...
10. In paragraph (1) of regulation 22 of the 1994 Regulations...
11. In paragraph (1) of regulation 23 of the 1994 Regulations...

SCHEDULE 2 — AMENDMENTS TO THE 1995 REGULATIONS

1. In regulation 2 of the 1995 Regulations (interpretation)—
2. After regulation 6 of the 1995 Regulations (withdrawals) there shall...
3. In the Table set out in the Schedule to the...

Explanatory Note

**Changes to legislation:**

There are currently no known outstanding effects for the The In Vitro Diagnostic Medical Devices Regulations 2000 (revoked).