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**Changes to legislation:** There are outstanding changes not yet made to Commission Decision of 7 May 2002 on common technical specifications for *in vitro*-diagnostic medical devices (notified under document number C(2002) 1344) (Text with EEA relevance) (2002/364/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) [View outstanding changes](#)

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Commission Decision of 7 May 2002 on common technical specifications  
for *in vitro*-diagnostic medical devices (notified under document  
number C(2002) 1344) (Text with EEA relevance) (2002/364/EC)

*Article 1*

The technical specifications set out in the Annex to this Decision are adopted as common technical specifications for *in vitro* diagnostic medical devices in list A of Annex II to Directive 98/79/EC.

*Article 2*

This Decision is addressed to the Member States.

**Changes to legislation:**

There are outstanding changes not yet made to Commission Decision of 7 May 2002 on common technical specifications for in vitro-diagnostic medical devices (notified under document number C(2002) 1344) (Text with EEA relevance) (2002/364/EC). Any changes that have already been made to the legislation appear in the content and are referenced with annotations.

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**Changes and effects yet to be applied to :**

- Annex Point 2 Text addition by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.4.2 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 2 Text replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 3 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.11 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.1 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 4 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.3 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Table 1 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Annex Point 3 Point 3.1.9 replacement by [EUDN 2020/350](#) Decision (This amendment by the EU not applied to legislation.gov.uk because it is brought into force after IP completion day.)
- Decision revoked by S.I. 2002/618, reg. 4H(1) (as inserted) by [S.I. 2019/791](#) reg. 3(7)
- Annex point 3.1.4 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(a)(i)
- Annex point 3.1.4 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(a)(ii)
- Annex point 3.1.8 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(b)(i)
- Annex point 3.1.8 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(b)(ii)
- Annex point 3.4.1 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(c)(i)
- Annex point 3.4.1 words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(c)(ii)
- Annex words substituted by [S.I. 2021/873](#) Sch. 2 para. 3(d)
- Art. 1 words inserted by [S.I. 2021/873](#) Sch. 2 para. 1
- Art. 2 omitted by [S.I. 2021/873](#) Sch. 2 para. 2