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)

ANNEX

COMMON TECHNICAL SPECIFICATIONS (CTS) FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

Acceptance criteria:
Qualifications:
Table 10 Batch release criteria for reagents and reagent products to determine...Specificity testing requirements on each reagent 1. Test reagents Only...
1. Test reagents
Acceptance criteria:
2. Control materials (red cells)

(**1**) OJ L 331, 7.12.1998, p. 1.

(**2**) OJ L 189, 20.7.1990, p. 17.

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.
View outstanding changes

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