**Draft for Public Comment**

Form 36

DPC: 25/30487902 DC

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Responsible committee: CH/212 IVDs

Interested committees:

Title: Draft BS ISO 24884 Electronic Instructions for Use for In Vitro Diagnostic Medical Devices — Minimum required information and means of delivery.

Please notify admin.start@bsigroup.com if you are aware of any keywords that might assist in clarifying or identifying the standard or of the content of this standard:

i) has any issues related to 3rd party IPR, patent or copyright
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**Introduction**

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

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**Template for comments and secretariat observations**

| Date: xx/xx/20xx | Document: ISO/DIS xxxx |
|---|---|

| 1 | 2 | (3) | 4 | 5 | (6) | 7 |
|---|---|---|---|---|---|---|
| **MB** | Clause No./ Subclause No./Annex **(e.g. 3.1)** | Paragraph/ Figure/Table/Note | **Type of comment** | **Commend (justification for change) by the MB** | **Proposed change by the MB** | **Secretariat observations on each comment submitted** |
| | 3.1 | Definition 1 | ed | Definition is ambiguous and needs clarifying. | Amend to read '...so that the mains connector to which no connection...' | |
| | 6.4 | Paragraph 2 | te | The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK. | Delete reference to UV photometer. | |

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# DRAFT International Standard

# ISO/DIS 24884

# Electronic Instructions for Use for In Vitro Diagnostic Medical Devices — Minimum required information and means of delivery

ICS: 11.100.10

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
**2025-10-13**

Voting terminates on:
**2026-01-05**

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