1 Scope
This International Standard specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus.

This International Standard is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.

This International Standard does not:
— provide a comprehensive evaluation of all possible factors that could affect the performance of these systems,
— pertain to glucose concentration measurement for the purpose of diagnosing diabetes mellitus,
— address the medical aspects of diabetes mellitus management,
— apply to measurement procedures with measured values on an ordinal scale (e.g. visual, semiquantitative measurement procedures), or to continuous glucose monitoring systems,
— apply to glucose meters intended for use in medical applications other than self-testing for the management of diabetes mellitus

2 Normative references
The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 13485, Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971, Medical devices — Application of risk management to medical devices
ISO 17511, In vitro diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials
ISO 18113-1, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements
ISO 18113-4, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing

ISO 18113-5, In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing


IEC 60068-2-64, Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance

IEC 61010-1, Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements

IEC 61010-2-101, Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

IEC 61326-1, Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements

IEC 61326-2-6, Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment

IEC 62366, Medical devices — Application of usability engineering to medical devices

EN 13612, Performance evaluation of in vitro diagnostic medical devices