

DIN EN ISO 15197:2015-12 (E)

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mel litus (ISO 15197:2013)

| Contents | | Page |
|--------------------|---|-------------|
| Foreword | | 3 |
| Introduction | | 5 |
| 1 | Scope | 6 |
| 2 | Normative references | 6 |
| 3 | Terms and definitions | 7 |
| 4 | Design and development | 13 |
| 4.1 | General requirements | 13 |
| 4.2 | Metrological traceability | 13 |
| 4.3 | Safety and risk management | 14 |
| 4.4 | Ergonomics and human factors | 15 |
| 4.5 | User verification requirements | 15 |
| 5 | Safety and reliability testing | 15 |
| 5.1 | General requirements | 15 |
| 5.2 | Protection against electric shock | 16 |
| 5.3 | Protection against mechanical hazards | 16 |
| 5.4 | Electromagnetic compatibility | 16 |
| 5.5 | Resistance to heat | 16 |
| 5.6 | Resistance to moisture and liquids | 16 |
| 5.7 | Protection against liberated gases, explosion and implosion | 17 |
| 5.8 | Meter components | 17 |
| 5.9 | Performance test | 17 |
| 5.10 | Mechanical resistance to vibration and shock | 17 |
| 5.11 | Equipment temperature exposure limits for storage | 18 |
| 5.12 | Equipment humidity exposure limits for storage | 18 |
| 6 | Analytical performance evaluation | 19 |
| 6.1 | General requirements | 19 |
| 6.2 | Measurement precision | 21 |
| 6.3 | System accuracy | 24 |
| 6.4 | Influence quantities | 30 |
| 6.5 | Stability of reagents and materials | 35 |
| 7 | Information supplied by the manufacturer | 35 |
| 7.1 | General requirements | 35 |
| 7.2 | Performance characteristics | 36 |
| 7.3 | Options for supplying instructions for use | 36 |
| 8 | User performance evaluation | 36 |
| 8.1 | General requirements | 36 |
| 8.2 | Acceptance criteria and evaluation of results | 37 |
| 8.3 | Selection and preparation of subjects | 37 |
| 8.4 | Execution of study protocol | 37 |
| 8.5 | Glucose reference values | 38 |
| 8.6 | Human factors | 38 |
| 8.7 | Data analysis and presentation of results | 38 |

| | | |
|------------|---|-----------|
| 8.8 | Evaluation of instructions for use | 39 |
| | Annex A (informative) Possible interfering substances | 40 |
| | Annex B (informative) Traceability chain | 41 |
| | Annex C (informative) Rationale for the analytical performance requirements | 43 |
| | Bibliography | 51 |
| | Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC | 50 |