DIN EN ISO 18113-2:2024-10 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)

Contents

Page

European foreword ... **4**

Annex ZA (informative) ... **5**

Foreword ... **9**

Introduction ... **10**

1 Scope ... **11**

2 Normative references ... **11**

3 Terms and definitions ... **11**

4 General ... **11**
4.1 Essential requirements ... 11
4.2 Identification of kit components ... 12

5 Content of the outer container label ... **12**
5.1 Manufacturer ... 12
5.2 Identification of the in vitro diagnostic (IVD) reagent ... 12
5.2.1 IVD reagent name ... 12
5.2.2 Batch code/lot number ... 12
5.2.3 Unique device identifier (UDI) ... 12
5.3 Contents ... 13
5.4 Intended use/Intended purpose ... 13
5.5 In vitro diagnostic use ... 13
5.6 Storage, transport, and handling conditions ... 13
5.7 Expiry date ... 13
5.8 Warnings and precautions ... 14

6 Content of the immediate container label ... **14**
6.1 General provisions ... 14
6.1.1 Single container ... 14
6.1.2 Small label ... 14
6.2 Manufacturer ... 14
6.3 Identification of the IVD reagent ... 14
6.3.1 IVD reagent or component name ... 14
6.3.2 Batch code/lot number ... 14
6.3.3 Unique device identifier (UDI) ... 15
6.4 Contents ... 15
6.5 In vitro diagnostic use ... 15
6.6 Storage and handling conditions ... 15
6.7 Expiry date ... 15
6.8 Warnings and precautions ... 15

7 Content of the instructions for use ... **15**
7.1 Manufacturer ... 15
7.2 Identification of the IVD reagent ... 16
7.3 Intended use/intended purpose ... 16
7.4 Principles of the examination method ... 16
7.5 Traceability of values assigned to calibrators and trueness-control materials ... 17
7.6 Components ... 17
7.7 Additional required equipment and/or materials ... 17
7.8 Reagent preparation ... 17

7.9 Storage and shelf life after first opening ... 18
7.10 Warnings and precautions and/or measures to be taken and limitations of use regarding the device ... 18
7.11 Primary sample collection, handling, and storage ... 18
7.12 Examination procedure ... 19
7.13 Control procedure ... 19
7.14 Calculation of examination results ... 19
7.15 Interpretation of results ... 19
7.16 Performance characteristics ... 19
7.16.1 Analytical performance characteristics ... 19
7.16.2 Clinical performance characteristics ... 20
7.16.3 Measuring interval ... 20
7.17 Biological reference intervals ... 20
7.18 Limitations of the examination procedure ... 20
7.19 Literature references ... 20
7.20 Document control ... 20
Bibliography ... **21**