DIN EN ISO 18113-4:2013-01 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (label ling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 General 6
4.1 Essential requirements 6
4.2 Identification of kit components 6
4.3 Presentation of the instructions for use 6

5 Content of the outer container label 6
5.1 Manufacturer 6
5.2 Identification of the IVD reagent 6
5.3 Contents 7
5.4 Intended use 7
5.5 In vitro diagnostic use 7
5.6 Storage and handling conditions 7
5.7 Expiry date 7
5.8 Warnings and precautions 8

6 Content of the immediate container label 8
6.1 General provisions 8
6.2 Manufacturer 8
6.3 Identification of the IVD reagent 8
6.4 Contents 8
6.5 In vitro diagnostic use 8
6.6 Storage and handling conditions 9
6.7 Expiry date 9
6.8 Warnings and precautions 9

7 Content of the instructions for use 9
7.1 Manufacturer 9
7.2 Identification of the IVD reagent 9
7.3 Intended use 9
7.4 Principles of the examination method 10
7.5 Components 10
7.6 Additional required equipment 10
7.7 Reagent preparation 10
7.8 Storage and shelf life after first opening 10
7.9 Warnings and precautions 10
7.10 Primary sample collection, handling and storage 11
7.11 Examination procedure 11
7.12 Control procedure 11
7.13 Reading of examination results 11
7.14 Interpretation of results 11
7.15 Performance characteristics 11

7.16 Biological reference intervals 12
7.17 Limitations of examination procedure 12
7.18 Literature references 12

Bibliography 13

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of the EU Directive 98/79/EC on "in vitro Diagnostic Medical Devices" 15