DIN EN ISO 18113-3:2024-10 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)

Contents

Page

Foreword 8

Introduction 9

1 Scope 10

European foreword 3

Annex ZA (informative) Relationship between this European StandardtheGeneral Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered 4

2 Normative references 10

3 Termsanddefinitions 10

4 Essential requirements 11

5 Labels and marking 11
5.1 General 11
5.2 Identification of the IVD instrument 11
5.2.1 IVD instrument name 11
5.2.2 Serial number 11
5.2.3 In vitro diagnostic use 11
5.2.4 Unique device identifier (UDI) 12

6 Elements of the instructions for use 12

7 Content of the instructions for use 13
7.1 Manufacturer 13
7.2 Identification of the IVD instrument 13
7.2.1 IVD instrument name 13
7.2.2 Module and software identification 13
7.3 Intended use/Intended purpose 14
7.4 Storage and handling 14
7.5 Warnings and precautions and/or measures to be taken and limitations of use regarding the instrument 14
7.6 Instrument installation 15
7.6.1 General 15
7.6.2 Action upon delivery 15
7.6.3 Site preparation prior to installation 15
7.6.4 Bringing into operation 15
7.7 Theory of operation 16
7.8 Functions 16
7.9 Limitations 16
7.10 Preparation prior to operation 16
7.11 Operating procedure 16
7.12 Control procedure 17
7.13 Calculation of examination results 17
7.14 Special functions 17

7.15 Emergency samples 17
7.16 Shut-down procedure 17
7.17 Disposal information 17
7.18 Maintenance 18
7.19 Troubleshooting 18
7.20 Document control 18

Bibliography 19