

# 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)

---

<b>Contents</b>	<b>Page</b>
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