

DIN EN ISO 18113-3:2013-01 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)

Contents		Page
Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	6
4	Essential requirements	6
5	Labels and marking	6
5.1	General	6
5.2	Identification of the IVD instrument	6
6	Elements of the instructions for use	6
7	Content of the instructions for use	7
7.1	Manufacturer	7
7.2	Identification of the IVD instrument	7
7.3	Intended use	7
7.4	Storage and handling	8
7.5	Warnings and precautions	8
7.6	Instrument installation	8
7.7	Theory of operation	9
7.8	Functions	9
7.9	Performance of the IVD instrument	9
7.10	Limitations of use	10
7.11	Preparation prior to operation	10
7.12	Operating procedure	10
7.13	Control procedure	10
7.14	Calculation of examination results	10
7.15	Special functions	11
7.16	Emergency primary samples	11
7.17	Shut-down procedure	11
7.18	Disposal information	11
7.19	Maintenance	11
7.20	Troubleshooting	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"		14