

ISO 18113-3:2009-12 (E)

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

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