

ISO 18113-1:2009-12 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	General requirements for information supplied by the manufacturer	17
4.1	General	17
4.2	Language	18
4.3	Symbols and identification colours	18
4.4	Values and nomenclature	18
4.5	Microbiological state	18
4.6	Instructions for use	18
4.7	Changes to the IVD medical device	19
4.8	Disclosure of residual risks	19
4.9	Identification of components	20
4.10	Assistance	20
Annex A (informative) Performance characteristics of IVD medical devices		21
Bibliography		45