

DIN EN ISO 18113-1:2010-05 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)

Contents		Page
Foreword		3
Introduction		4
1	Scope	6
2	Normative references	6
3	Terms and definitions	7
4	General requirements for information supplied by the manufacturer	22
4.1	General	22
4.2	Language	23
4.3	Symbols and identification colours	23
4.4	Values and nomenclature	23
4.5	Microbiological state	23
4.6	Instructions for use	23
4.7	Changes to the IVD medical device	24
4.8	Disclosure of residual risks	24
4.9	Identification of components	25
4.10	Assistance	25
Annex A (informative) Performance characteristics of IVD medical devices		26
Bibliography		50
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"		55