ISO 18113-1:2022-10 (E)

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

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Terms and definitions 1
3.1 General terms and definitions for use with in vitro diagnostic medical devices 2
3.2 Performance characteristic terms and definitions 22

4 General requirements for information supplied by the manufacturer 40
4.1 General 40
4.2 Language 41
4.3 Symbols and identification colours 41
4.4 Values and nomenclature 41
4.5 Microbiological state 42
4.6 Instructions for use 42
4.7 Changes to the IVD medical device 43
4.8 Disclosure of residual risks 43
4.9 Identification of components 43
4.10 Assistance 43

Annex A (informative) Performance characteristics of IVD medical devices 44

Bibliography 50