ISO 19001:2013-03 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic reagents for staining in b iology

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements for information supplied by the manufacturer 3
4.1 General requirements 3
4.2 Additional requirements for specific kinds of reagent 4

Annex A (informative) Examples of information supplied by the manufacturer with reagents commonly used in biological staining procedures 7

Bibliography 13