DIN EN ISO 19001:2013-07 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer with in vitro diagnostic re agents for staining in biology (ISO 19001:2013)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 Requirements for information supplied by the manufacturer 7
4.1 General requirements 7
4.2 Additional requirements for specific kinds of reagent 8

Annex A (informative) Examples of information supplied by the manufacturer with reagents commonly used in biological staining procedures 11

Bibliography 17