ISO 8871-2:2003-10 (E)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 2: Identification and characterization

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Tests 1

4 Preparation of samples for testing 3

5 Reagents and materials 4

Annex A (informative) Identification of elastomeric material by pyrolysis IR 5

Annex B (informative) Determination of compression set 7

Annex C (informative) Swelling behaviour in oils 9

Annex D (informative) Development of a fingerprint by gas chromatography 11

Annex E (informative) Analysis of volatile components by headspace gas chromatography 13

Annex F (informative) Determination of residual moisture 15

Annex G (informative) Determination of a fingerprint by thermal gravimetry (TG) 16

Bibliography 20