

ISO 8871-5:2016-10 (E)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 5: Functional requirements and testing

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Requirements	2
4.1	Penetrability	2
4.2	Fragmentation	2
4.3	Self-sealing and aqueous solution tightness	2
4.4	Aqueous solution tightness	2
5	Preparation of elastomeric closures for testing	2
5.1	Sampling	2
5.2	Cleaning	2
5.3	Sterilization	2
Annex A (normative) Test for penetrability		3
Annex B (normative) Test for fragmentation		4
Annex C (normative) Test for self-sealing and dye solution tightness		6
Annex D (normative) Test for dye solution tightness		8
Bibliography		10