

# ISO 8871-5:2025-03 (E)

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

---

<b>Contents</b>		<b>Page</b>
<b>Foreword</b> .....		<b>iv</b>
<b>Introduction</b> .....		<b>vi</b>
<b>1 Scope</b> .....		<b>1</b>
<b>2 Normative references</b> .....		<b>1</b>
<b>3 Terms and definitions</b> .....		<b>1</b>
<b>4 Requirements</b> .....		<b>2</b>
4.1 Penetrability.....		2
4.2 Fragmentation.....		2
4.3 Self-sealing.....		2
4.4 Dye solution tightness.....		2
<b>5 Preparation of closures for testing</b> .....		<b>2</b>
5.1 Sampling.....		2
5.2 Cleaning.....		3
5.3 Sterilization.....		3
<b>Annex A (normative) Test for penetrability</b> .....		<b>4</b>
<b>Annex B (normative) Test for fragmentation</b> .....		<b>5</b>
<b>Annex C (normative) Test for self-sealing</b> .....		<b>7</b>
<b>Annex D (normative) Test for dye solution tightness</b> .....		<b>9</b>
<b>Bibliography</b> .....		<b>11</b>