

DIN EN ISO 8871-3:2019-08 (E)

Elastomeric parts for parenterals and for devices for pharmaceutical use - Part 3:
Determination of released-particle count (ISO 8871-3:2003 + Amd 1:2018) (includes
Amendment A1:2019)

| Contents | | Page |
|---|---|-------------|
| Foreword | | 3 |
| !European foreword to Amendment A1" | | 4 |
| !Foreword to Amendment 1" | | 5 |
| Introduction | | 6 |
| 1 | Scope | 7 |
| 2 | Normative references | 7 |
| 3 | Determination of visible-particle count | 7 |
| 3.1 | Principle | 7 |
| 3.2 | Classification | 7 |
| 3.3 | Apparatus and materials | 7 |
| 3.4 | Preparation for the test | 8 |
| 3.5 | Test | 9 |
| 3.6 | Test report | 9 |
| 4 | Determination of subvisible-particle count | 9 |
| 4.1 | Principle | 9 |
| 4.2 | Classification | 9 |
| 4.3 | Apparatus and materials | 10 |
| 4.4 | Preparations | 10 |
| 4.5 | Test | 10 |
| 4.6 | Test report | 11 |
| | Bibliography | 12 |