

ISO 11979-6:2014-10 (E)

Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing

| Contents | | Page |
|--|---------------------------------|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Requirements | 1 |
| 4.1 | General | 1 |
| 4.2 | Materials and methods | 2 |
| 4.3 | Product stability | 2 |
| 4.4 | Package integrity | 4 |
| 4.5 | Transport stability | 5 |
| 4.6 | Results | 5 |
| 5 | Test methods and sampling | 6 |
| Annex A (informative) Shelf-life study example | | 7 |
| Annex B (informative) Tests for shelf-life studies | | 10 |
| Bibliography | | 11 |