

DIN EN 868-4:2025-09 (E)

Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods

| Contents | | Page |
|--|--|-------------|
| European foreword | | 3 |
| Introduction | | 5 |
| 1 | Scope | 6 |
| 2 | Normative references | 6 |
| 3 | Terms and definitions | 7 |
| 4 | General requirements | 7 |
| 5 | Construction and design | 7 |
| 5.1 | General | 7 |
| 5.2 | Bottom seal formation | 8 |
| 5.3 | Back seam construction | 8 |
| 5.4 | Process indicator | 8 |
| 5.5 | Seal strip | 8 |
| 6 | Performance requirements and test methods | 8 |
| 7 | Sterilization compatibility | 9 |
| 8 | Labelling | 9 |
| 8.1 | General | 9 |
| 8.2 | Paper bags | 9 |
| 8.3 | Sales packaging | 10 |
| 9 | Information to be provided | 10 |
| 9.1 | Information on the sealing or closure conditions | 10 |
| 9.2 | Environmental declarations | 10 |
| Annex A (normative) Method for the determination of pH value, chloride and sulfate in paper bags | | 12 |
| Annex B (normative) Method for the determination of the tensile strength of the back seam joint in paper bags | | 14 |
| Annex C (informative) Repeatability and reproducibility of test methods | | 16 |
| Annex D (informative) Environmental aspects | | 17 |
| Bibliography | | 20 |