

# DIN EN 868-5:2019-03 (E)

## Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

---

<b>Contents</b>	<b>Page</b>
European foreword.....	3
Introduction .....	5
1 Scope.....	6
2 Normative references.....	6
3 Terms and definitions .....	6
4 Requirements .....	7
4.1 General.....	7
4.2 Materials.....	7
4.2.1 Porous material .....	7
4.2.2 Plastic film .....	7
4.3 Construction and design.....	8
4.4 Process indicator.....	8
4.5 Performance requirements and test methods .....	8
4.6 Marking.....	9
4.6.1 Pouches and reels .....	9
4.6.2 Transport and/or storage packaging .....	10
5 Information to be supplied by the manufacturer.....	10
Annex A (informative) Details of significant technical changes between this document and the previous edition .....	11
Annex B (normative) Method for the determination of resistance to the intended sterilization process.....	12
Annex C (normative) Method for the determination of pinholes in plastic laminate .....	13
Annex D (normative) Method for the determination of the strength of the seal for pouches and reel material.....	15
Annex E (normative) Method for the determination of peel characteristics of paper/plastic laminate products.....	18
Annex F (normative) Method for the determination of fibre orientation .....	20
Bibliography.....	21