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

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

## Contents

Page


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