

DIN EN 868-7:2017-05 (E)

Packaging for terminally sterilized medical devices - Part 7: Adhesive coated paper for low temperature sterilization processes - Requirements and test methods

Contents		Page
European foreword		4
Introduction		5
1 Scope		6
2 Normative references		6
3 Terms and definitions		7
4 Requirements		7
5 Information to be supplied by the manufacturer		9
Annex A (informative) Details of significant technical changes between this European Standard and the previous edition		10
Annex B (normative) Method for the determination of water repellency		11
B.1 Apparatus		11
B.2 Reagent		11
B.3 Procedure		11
B.4 Repeatability and reproducibility		11
B.5 Test report		12
Annex C (normative) Method for the determination of pore size		13
C.1 Principle		13
C.2 Test liquid		13
C.3 Apparatus		13
C.4 Preparation of test specimens		15
C.5 Procedure		15
C.6 Result		16
C.6.1 Calculation and expression of results		16
C.6.2 Derivation of formula for calculation of equivalent pore radius		16
C.7 Repeatability and reproducibility		17
C.8 Test report		17
Annex D (normative) Method for the determination of regularity of seal adhesive coatings on paper		18
D.1 Principle of the method		18
D.2 Apparatus		18
D.3 Procedure		18
D.4 Test report		18
Annex E (normative) Method for the determination of mass per unit area of uncoated paper and adhesive coating		19
E.1 Units		19
E.2 Principle of the method		19

E.3	Apparatus	19
E.4	Procedure	19
E.5	Results	20
E.6	Test report	20
Annex F (normative) Method for the determination of seal strength and mode of specimen failure ..		21
F.1	Principle of the method	21
F.2	Test method	21
F.3	Preparation of test-specimen	21
F.4	Procedure	21
F.5	Test report	22
Annex G (informative) Repeatability and reproducibility of test methods		23
Bibliography		25