

DIN EN 868-8:2019-03 (E)

Packaging for terminally sterilized medical devices - Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods

Contents	Page
European foreword.....	4
Introduction	6
1 Scope	7
2 Normative references.....	7
3 Terms and definitions	7
4 Requirements	8
5 Information to be supplied by the manufacturer.....	11
Annex A (informative) Details of significant technical changes between this document and the previous edition	12
Annex B (informative) Guidance on dimensions	13
Annex C (normative) Carrying device strength test	14
C.1 Procedure.....	14
C.2 Result.....	14
Annex D (normative) Stacking test - Procedure.....	15
Annex E (normative) Stacking device capability test.....	16
E.1 Apparatus.....	16
E.2 Procedure.....	16
Annex F (normative) Determination of sterilization performance	17
F.1 Apparatus.....	17
F.2 Procedure.....	17
F.3 Results.....	17
Annex G (normative) Load dryness tests.....	18
G.1 Apparatus.....	18
G.2 Loads.....	18
G.2.1 Metal	18
G.2.2 Textile.....	18
G.3 Procedure.....	18
G.3.1 Metal Load.....	18
G.3.2 Textile load.....	18
G.4 Results.....	19
G.4.1 Metal load.....	19
G.4.2 Textile load.....	19

Annex H (informative) Guidance on determination of service life with respect to sterilization.....	20
H.1 Test specimen	20
H.2 Apparatus	20
Bibliography	21