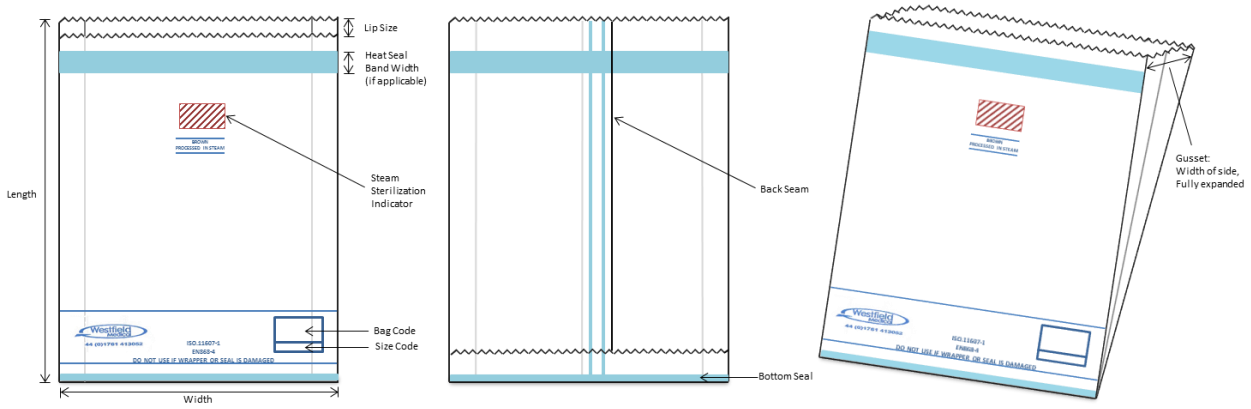
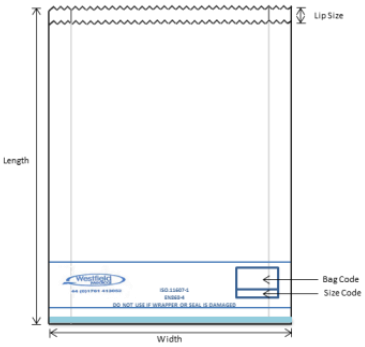
Technical Datasheet (Product)
Stock Sterilisation Bags

General Description



FRONT BACK GUSSET



Westfield Medical sterilisation bags are available in a range of sizes, with either heat seal (HS) closures, as shown above, or as plain closures (PC), shown right. The bag features a lip to assist filling, with serrated edges for safety.

Custom print configurations are also available.

The HS bags can be sealed using medical heat sealing equipment at 180°C - 200°C and feature a steam sterilisation process indicator.

Plain closure bags can be sealed using autoclave tape.

The bag is suitable for Steam, Ethylene Oxide, Formaldehyde and Irradiation sterilisation processes.

Sizes available

Size Code	Width ±3mm	Gusset ±3mm	Length ±10mm	Size Code	Width ±3mm	Gusset ±3mm	Length ±10mm
A	90	50	170	N	300	125	610
B	90	50	250	O	180	75	530
C	110	30	190	P	190	65	330
D	140	75	250	Q	110	45	190
E	190	65	250	R	125	50	250
F	140	50	330	S1	125	90	250
H	180	95	380	T	380	125	510
J	100	50	170	T35	380	125	610
K1	150	40	330	U	75	25	480
L	250	100	380	V1	125	30	170
M	300	75	530	W	125	50	560

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FM01170 MD591173

Materials

Paper: 60gsm medical grade paper in accordance with EN868-3:2017.
Adhesives: Blue, water based, autoclave resistant adhesive forming side seam, bottom seal and heat seal. Colourless water based autoclave resistant adhesive securing bottom flap.

Regulatory Compliance

The product conforms to the Medical Devices Directive 93/42/EEC and subsequent amendments as a class I non-sterile device. The outer box of the product accordingly carries the CE mark.
Process indicator, where printed, conforms to ISO 11140-1:2014 as Class 1 indicator.
The product also conforms to ISO11607-1:2019 and EN868-4:2017.

The materials used in the product met the requirements of:

FDA CFR 175.105, 175.300, 176.170, 176.180, 177.1210
BfR XXXVI
EC/1935/2004, EC2023/2006

The product is manufactured under a quality management system that conforms to ISO9001:2015 and ISO13485:2016 and the manufacturing process is validated to ISO11607-2:2019.

This product has an Active Life of up to 5 years from the date of manufacture, dependant on storage conditions. For more information, please refer to Westfield Medical Advice Sheet 1: Active Life of Single-Use Sterilisation Packaging Materials, and Advice Sheet 20: Storage Conditions of Westfield Medical Packaging Products.

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