PRODUCT SPECIFICATION SHEET

1. PRODUCT: BURNSHIELD DRESSING 100 mm x 100 mm (4" x 4")

PRODUCT CODE

L901111

UDI CODE

6007645001380

TRADE NAME

Burnshield

DOSAGE FORM

DRESSING 100 mm x 100 mm (4" x 4") wetted with 40 g - 42 g of

Burnshield Gel

APPLICATION

Emergency treatment of all types of wounds

DESCRIPTION

Polyurethane foam material wetted with Burnshield Gel contained in

a multilayered aluminium pouch

2. PRODUCT DESCRIPTION

Burnshield Dressings are made from a Polyurethane foam material. The foam is place in a multilayer aluminium pouch, wetted with 40 g - 42 g of Burnshield Gel, and sealed.

3. PRODUCT SPECIFICATIONS

PROPERTY	SPECIFICATION
Appearance of Gel	Soft gel of even consistency
Colour of Gel	White to off-white
Appearance of Polyurethane foam material	Soft foam
Colour of Polyurethane foam material	White to off-white
Weight of Dry Polyurethane foam	0.85 g – 0.95 g
Odour of Gel	Of Tea-Tree Oil
Dressing Dimensions	Length 100 mm - 110 mm Width 100 mm - 110 mm Thickness 3 mm - 4 mm
Gel fill weight	40 g – 42 g
Viscosity (Brookfield - Spindle 6, 20rpm, 25°C)	Before Sterilisation minimum 25 000 cPs
	After Sterilisation minimum 7 000 cPs
Density (Anton Paar, 20 °C)	0.975 g/cm ³ – 1.025 g/cm ³
pH (Metrohm 744 Combined Glass Electrode pH Meter)	Before Sterilisation 5.5 – 7.5
	After Sterilisation 5.0 – 7.5
Sterility	Sterile
Content of Melaleuca Oil	$0.927 - 1.133\% (1.03 \pm 10\%) (w/w)$

Rev.4

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Prepared By: (Quality Assurance Manager) Approved By: (Managing Director)