



EMERGENCY BURNCARE

(PTY) LTD
Reg No: 91-29023-23

MEDOPARK, BLOCK 3
NO.1 MANCHESTER ROAD, WADEVILLE
SOUTH AFRICA

P. O. BOX 14737
WADEVILLE 1422
SOUTH AFRICA
TEL: +27 (0)11 827 4140
FAX: +27 (0)11 827 9009
EMAIL: max@burnshield.com

MANUFACTURERS OF BURNSHIELD® EMERGENCY BURNCARE PRODUCTS

BURNSHIELD TECHNICAL FILE DECLARATION OF CONFORMITY

SECTION	D	VERSION	17.0	DATE	23.05.2017
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DECLARATION OF CONFORMITY

We hereby confirm that **BURNSHIELD (PTY) LTD** of 1 Manchester Road, Wadeville, Germiston, South Africa, 1422 represented in the European Community by **BURNSHIELD INTERNATIONAL LIMITED** at Beaumont House, Paragon Avenue, Wakefield, WF1 2UF, DX15011, United Kingdom, declare that the Products listed on this schedule meet the requirements of the Medical Device Directive 93/42/EEC and all subsequent amendments including 2007/47/EC as detailed in our Product Technical File (current Version Index 11).

We further declare that our chosen conformance route is Annex II and that our Notified Body is ICIM Spa, Identification Number 0425.

PRODUCTS CLASS IIb (classified according to Rule 4)

Burnshield Dressings	10cm x 10cm 20cm x 45cm Digit (2.5cm x 0.5m) Limb (5.0cm x 1.0m)	20cm x 20cm 60cm x 40cm 20cm x 45cm (Face Mask) 60cm x 40cm (Face Mask)
Contour Dressings	1.0m x 1.0m and 1.0m x 2.0m	
Cotton and Wool Blankets	80cm x 80cm, 1.6m x 1.2m, 1.6m x 1.8m and 1.6m x 2.45m	
Burnshield Hydrogel	Bottles: 50ml, 75ml and 125ml	
Burnshield Hydrogel Tubes	Tubes: 10ml and 25ml	
Burnshield Burnblott Sachets	Sachets 0.9ml and 3.5ml	
Solace Aftersun	Tube: 100ml	
Burnshield Hydrogel Multi-use	Bottles: 50ml, 75ml and 125ml	
Burnshield Burn Vests	6 – 12 months, 2 – 3 years and 4 – 5 years	
Various First Aid and Burn Kits	Various Kits containing First Aid Consumables including various Burnshield Products	

Compiled By 
M. Di Domenico (Managing Director)