BURNSHIELD®
FOR THE EMERGENCY CARE OF BURNS & SCALDS

Burnshield (Pty) Ltd
1 Manchester Road
Medopark Block 3
Wadeville,1428
South Africa

Co. Reg No.: 1997/008394/07
Tel: +27 (0) 11 827 4140
Fax: +27 (0) 11 827 9009
Email: contact@burnshield.com
Website: www.burnshield.com

BURNSHIELD TECHNICAL FILE

DECLARATION OF CONFORMITY

SECTION D	VERSION 25	DATE 30.05.2022

DECLARATION OF CONFORMITY

We hereby confirm that **BURNSHIELD (PTY) LTD** of 1 Manchester Road, Medopark Block 3, Wadeville, 1428, South Africa, represented in the European Community by:
BURNSHIELD EUROPE B.V. at Einsteinstraat 5, 2181 AA, Hillegom, The Netherlands,
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 28). Certificate No. 0425 – MED – 002485-01.

We further declare that our chosen conformance route is Annex II and that our Notified Body is ICIM Spa, Identification Number 0425. Certificate Issue date: 05/09/2017.

PRODUCTS CLASS IIb (classified according to Rule 4)

	Trade Name	Product Code	Barcode	GMDN Code	GMDN Term
1	Burnshield Dressing 100mm x 100mm (4" x 4")	901111	6007645001380	47693	Burn dressing, polyurethane
2	Burnshield Dressing 200mm x 200mm (8" x 8")	900906	6007645001397	47693	Burn dressing, polyurethane
3	Burnshield Dressing 200mm x 450mm (8" x 18")	901001	6007645001410	47693	Burn dressing, polyurethane
4	Burnshield Face Mask Dressing 200mm x 450mm (8" x 18")	901000	6007645001458	47693	Burn dressing, polyurethane
5	Burnshield Dressing 600mm x 400mm (24" x 16")	901007	6007645001403	47693	Burn dressing, polyurethane
6	Burnshield Face Mask Dressing 600mm x 400mm (24" x 16")	901135	6007645003957	47693	Burn dressing, polyurethane
7	Burnshield Digit Dressing 25mm x 500mm (1" x 20")	901130	6007645001434	47693	Burn dressing, polyurethane
8	Burnshield Limb Dressing 50mm x 1m (2" x 40")	901131	6007645001427	47693	Burn dressing, polyurethane
9	Burnshield Burn Sachet 3.5ml (1/8oz)	550004	6007645000215	47694	Burn gel
10	Burnshield Burn Sachet 0.9g (1/32oz)	550021	6007645006057	47694	Burn gel
11	Burnshield Hydrogel Spray Bottle 125ml (4.5oz)	550003	6007645000192	47694	Burn gel
12	Burnshield Hydrogel Spray Bottle 75ml (2.7oz)	550082	6007645004305	47694	Burn gel
13	Burnshield Hydrogel Spray Bottle 50ml (1.8oz)	550020	6007645006040	47694	Burn gel
14	Burnshield Hydrogel Bottle 50ml (1.8oz)	550000	6007645000123	47694	Burn gel
15	Burnshield Hydrogel Tube 125ml (4.5oz)	550027	6007645007443	47694	Burn gel
16	Burnshield Hydrogel Tube 25ml (0.85oz)	550009	6007645005302	47694	Burn gel
17	Burnshield Hydrogel Tube 10ml (0.35oz)	550010	6007645004596	47694	Burn gel
18	Burnshield Cartridge 150g (5.29oz)	550023	6007645007153	47694	Burn gel
19	Burnshield Cartridge 1.2kg (42.32oz)	550022	6007645007078	47694	Burn gel
20	Burnshield Contour Dressing 1m x 1m (40" x 40")	881006	6007645003520	47692	Burn dressing, cotton
21	Burnshield Contour Dressing 1m x 2m (40" x 80")	881007	6007645003537	47692	Burn dressing, cotton
22	Burnshield Wool Blanket 2.45m x 1.6m (98" x 64")	881001	6007645000161	47696	Pure wool burn sheet
23	Burnshield Wool Blanket 1.2m x 1.6m (48" x 64")	881003	6007645000222	47696	Pure wool burn sheet
24	Burnshield Wool Blanket 1.6m x 1.8m (64" x 71")	881010	6007645007917	47696	Pure wool burn sheet
25	Burnshield Burn Vest 6-12 Months	881080	6007645004329	47692	Burn dressing, cotton
26	Burnshield Burn Vest 24-36 Months	881085	6007645004336	47692	Burn dressing, cotton
27	Burnshield Burn Vest 4-5 Years	881090	6007645004343	47692	Burn dressing, cotton
28	Solace Aftersun Spray 125ml (4.5oz)	551015	6007645002851	47694	Burn gel

Compiled By: S. Protheroe (Regulatory Affairs Manager)	Approved By: M. Di Domenico (Managing Director)