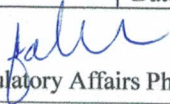
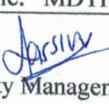


MEDICAL DEVICE TECHNICAL FILE			Page 1 of 1
ANX-07 DECLARATION OF CONFORMITY – BURNSHIELD			
Revision: 1	Date: 09.09.2024	File: MDTF	
Prepared By:  K. Lam (Regulatory Affairs Pharmacist)		Approved By:  A. Cassim (Quality Management Representative)	



We hereby confirm that **BURNSHIELD (PTY) LTD**, located at 1 Manchester Road, Medopark Block 3, Wadeville, Germiston, South Africa, 1428 with SRN Number ZA-MF-000018376 represented in the European Community by its EC REP **BURNSHIELD EUROPE B.V.**, located at Einsteinstraat 5, 2181 AA, Hillegom, The Netherlands, declares:

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 on Medical Devices.

We further declare that our chosen conformance route is Annex II and that our Notified Body is ICIM Spa, Identification Number 0425, issued under European Conformity: Medical Device Directive 93/42/EEC and all subsequent amendments including 2007/47/EC on Medical Device.

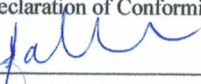
Certificate number: 0425 – MED – 002485-01. Expiry Date: 31/12/2028.

PRODUCTS CLASS IIB (classified according to Rule 4 of Annex II in MDD)

	Trade Name	Product Code	Barcode	GMDN Code	Basic UDI-DI
1	Burnshield Dressing 100mm x 100mm (4" x 4")	901111	6007645001380	47693	6007645BurnshieldDresAR
2	Burnshield Dressing 200mm x 200mm (8" x 8")	900906	6007645001397	47693	6007645BurnshieldDresAR
3	Burnshield Dressing 200mm x 450mm (8" x 18")	901001	6007645001410	47693	6007645BurnshieldDresAR
4	Burnshield Face Mask Dressing 200mm x 450mm (8" x 18")	901000	6007645001458	47693	6007645BurnshieldDresAR
5	Burnshield Dressing 600mm x 400mm (24" x 16")	901007	6007645001403	47693	6007645BurnshieldDresAR
6	Burnshield Face Mask Dressing 600mm x 400mm (24" x 16")	901135	6007645003957	47693	6007645BurnshieldDresAR
7	Burnshield Digit Dressing 25mm x 500mm (1" x 20")	901130	6007645001434	47693	6007645BurnshieldDresAR
8	Burnshield Limb Dressing 50mm x 1m (2" x 40")	901131	6007645001427	47693	6007645BurnshieldDresAR
9	Burnshield Burnblott Sachet 3.5ml (1/8oz)	550004	6007645000215	47694	6007645BurnshieldSachAH
10	Burnshield Burnblott Sachet 0.9g (1/32oz)	550021	6007645006057	47694	6007645BurnshieldSachAH
11	Burnshield Hydrogel Spray Bottle 125ml (4.5oz)	550003	6007645000192	47694	6007645BurnHydroBottlR8
12	Burnshield Hydrogel Spray Bottle 75ml (2.7oz)	550082	6007645004305	47694	6007645BurnHydroBottlR8
13	Burnshield Hydrogel Spray Bottle 50ml (1.8oz)	550020	6007645006040	47694	6007645BurnHydroBottlR8
14	Burnshield Hydrogel Bottle 50ml (1.8oz)	550000	6007645000123	47694	6007645BurnHydroBottlR8
15	Burnshield Hydrogel Tube 25ml (0.85oz)	550009	6007645005302	47694	6007645BurnHydroTubesUX
16	Burnshield Hydrogel Tube 10ml (0.35oz)	550010	6007645004596	47694	6007645BurnHydroTubesUX
17	Burnshield Cartridge 150g (5.29oz)	550023	6007645007153	47694	6007645BurnshieldCart96
18	Burnshield Cartridge 1.2kg (42.32oz)	550022	6007645007078	47694	6007645BurnshieldCart96
19	Burnshield Contour Dressing 1m x 1m (40" x 40")	881006	6007645003520	47692	6007645BurnshieldContAY
20	Burnshield Contour Dressing 1m x 2m (40" x 80")	881007	6007645003537	47692	6007645BurnshieldContAY
21	Burnshield Wool Blanket 2.45m x 1.6m (98" x 64")	881001	6007645000161	47696	6007645BurnshieldWoolEX
22	Burnshield Wool Blanket 1.2m x 1.6m (48" x 64")	881003	6007645000222	47696	6007645BurnshieldWoolEX
23	Burnshield Wool Blanket 1.6m x 1.8m (64" x 71")	881010	6007645007917	47696	6007645BurnshieldWoolEX
24	Burnshield Burn Vest 6-12 Months	881080	6007645004329	47692	6007645BurnshieldVestE2
25	Burnshield Burn Vest 24-36 Months	881085	6007645004336	47692	6007645BurnshieldVestE2
26	Burnshield Burn Vest 4-5 Years	881090	6007645004343	47692	6007645BurnshieldVestE2

This Declaration of Conformity applies to all the products listed on this Schedule produced by Burnshield (Pty) Ltd. Each lot produced may be issued with a valid Certificate of Analysis on request.

This Declaration of Conformity is issued under the sole responsibility of Burnshield (Pty) Ltd and authorized by:


K. Lam
(Regulatory Affairs Pharmacist)

Date: 9/09/2024
Place: Wadeville, Germiston