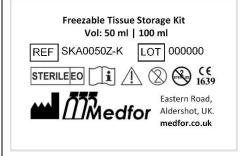


## **TECHNICAL DATA SHEET**

TDS No 012 Issue 06

Plastic C	ontainers for Laboratories									
1	Description		Freezable T	Freezable Tissue Storage Kit, double bagged, Sterile EO						
2	Ref(s)				Blank label on outer pot	Pre-printed label on both pots		both pots		
			50 ml / 100 ml			SKA0050Z-K				
			100 ml / 30	0 ml		SKA01002	Z-K			
			250 ml/500 ml		S600-K					
			300 ml / 500 ml			SKA0300Z-K				
			500 ml/1000 ml   S610-K   SKA0500Z-K							
3	Regulatory		Conform to the relevant provisions of the EC Council Directive							
			93/42/EEC, dated 14th June 1993 and all the relevant							
			amendments. Annex V sterility aspects only. Medfor is registered							
4			to ISO 13485:2016.							
4	CE marking	CE 1639 (Class IIa medical device suitable for storage of human								
5	Manufacture		tissue for in vivo use)							
5	ivianuracture		Product assembled in class 7 cleanroom in accordance with BS/EN/ISO 14644-1:2015.							
6	Dimensions		<i>B3</i> / £14/130	Height	Diameter	Internal	Nominal	Brimful		
O	and Volume			includin		neck	capacity	capacity		
				g cap	cap(mm)	bore	(ml)	(ml)		
				(mm)		(mm)		, ,		
		SKA0050Z-K	Inner pot	57	41.4	34.8	50	50		
			Outer pot	63	55.4	48.6	100	105		
		SKA0100Z-K	Inner pot	63	55.4	48.6	100	105		
			Outer pot	83	80.2	72.1	300	312		
		S600-K	Inner pot	87	72.2	64.0	250	257		
			Outer pot	110	95.2	86.5	500	587		
		SKA0300Z-K	Inner pot	83	80.2	72.1	300	312		
			Outer Pot	110	95.2	86.5	500	587		
		S610-K	Inner pot	110	95.2	86.5	500	587		
		SKA0500Z-K	Outer pot	127	117.8	108.7	1000	1096		
7	Material composition		Jar	Nati	Natural polypropylene					
			Сар							
8	Biocompatibili	Literary review of comparative products and historic usage of this type of product sold by Medfor has established that the kits do not affect the quality or integrity of tissue stored within them.								
9	Type of closur	e	Tamper-evident screw cap							
10	Sterilisation		Sterilisation has been carried out using ethylene oxide in accordance with ISO 11135-1:2014.							
11	Labelling	Case, pack and product labelling in accordance with ISO 15223-1:2016								
12	Temperature i	range	-80° C to 75° C. Can be stored to -80° C for up to five years.							
13	Autoclavability	У	Not suitable	Not suitable.						
14	Physical resist	Flexible to rigid, good mechanical resistance, high chemical resistance								
15	Shelf life (befo	Packs contents remain sterile for up to 3 years from date of manufacture or until pack is opened or breached, whichever occurs first.								

16	Pack quantities	SKA0050Z-K	10 packs per case	Pack description: 50 ml pot inside 100 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.			
		SKA0100Z-K	10 packs per case	Pack description: 100 ml pot inside 300 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.			
		S600-K	10 packs per case	Pack description: 250ml pot inside 500ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Outer pot labelled.			
		SKA0300Z-K	10 packs per case	Pack description: 300 ml pot inside 500 ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.			
		S610-K	8 packs per case	Pack description: 500ml pot inside 1000ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Outer pot labelled.			
		SKA0500Z-K	8 packs per case	Pack description: 500ml pot inside 1000ml pot with both caps separate within inner pack so ethylene oxide unimpeded during sterilisation process. Both pots labelled.			
17	7 Storage conditions before		Temperature: 10°C to 35°C				
	packs opened			dity: 20% to 80%			
18	18 Other information			dry conditions away from direct sunlight.			
19	Other information		<ul> <li>Do not use if package damaged.</li> <li>Single Use only. Do not reuse due to risk of cross-infection.</li> <li>Do not irradiate</li> </ul>				
			<ul> <li>The range of Tissue transport freezing storage pots and Tissue transport storage pots are both DEHP and Latex Free</li> <li>The range does not contain tissues of animal origin nor human blood derivative products.</li> <li>The devices do not require to be connected to other devices in</li> </ul>				
			order to be used.				
19	Product labels		SKA0050Z-K – mm wide x 40	image of label applied to both pots (actual size 60 mm high):			

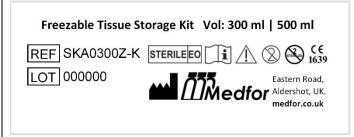


SKA0100Z-K – image of label applied to both pots (actual size 60 mm wide x 40 mm high):



S600-K – label size on outer pot is 185 mm wide x 55 mm high (no image)

SKA0300-K – image of label applied to both pots (actual size 90 mm wide x 35 mm high):



S610-K-label size on outer pot is 185 mm wide x 55 mm high (no image).

SKA0500Z-K – image of label applied to both pots (actual size 90 mm wide x 35 mm high):

