

## **TECHNICAL DATA SHEET**

TDS No 012 Issue 07

ontainers for Laboratories									
Description		Freezable Tissue Storage		ge Kit, doubl	Kit, double wrapped, Sterile EO				
Ref(s)		Pot sizes:	Pot sizes:		Ref:				
		50 ml / 100 ml		SKA0050Z	SKA0050Z-K				
		100 ml / 30	100 ml / 300 ml		SKA0100Z-K				
		300 ml / 500 ml		SKA0300Z	SKA0300Z-K				
		500 ml/100	500 ml/1000 ml SKA0500Z-K						
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 CE marking		to ISO 13485:2016.							
CE marking		CE 1639 (Class IIa medical device suitable for storage of human							
		tissue for in vivo use)							
Manufacture			Product assembled in class 7 cleanroom in accordance with						
			_				Brimful 		
and Volume			-				capacity		
			(mm)	mm)		(mi)	(ml)		
	CKAOOEOZ K	Innor not	E 7	11 1		FO	50		
	SKAUUSUZ-K						105		
	CK 4 0 1 0 0 7 K	•				1			
	SKAU100Z-K	-			1		105		
	CKV03002 K						312 312		
							587		
		_					-		
	SKA0500Z-K	· ·					587		
		-				1000	1096		
7 Material composition			Jar Natural polypropylene						
		<u> </u>	Cap White HDPE						
Biocompatibili	ty								
			type of product sold by Medfor has established that the kits do not						
+									
Sterilisation		<b>3</b> ,							
Laballing									
Labelling									
Tomporaturo	-								
'					<b>S.</b>				
i ilysical resistance									
Shelf life (before use)									
Silen ine (belo	Silen line (belone use)		·						
Pack	Pack SKA00507-K								
	3KA00302-K			50 ml pot inside 100 ml pot with both caps separate within inner pack so ethylene oxide					
4									
			unimpeded during sterilisation process. Both pots						
	Description Ref(s)  Regulatory  CE marking  Manufacture  Dimensions and Volume  Material comp  Biocompatibili  Type of closure  Sterilisation  Labelling  Temperature r  Autoclavability Physical resists	Description Ref(s)  Regulatory  CE marking  Manufacture  Dimensions and Volume  SKA0050Z-K  SKA0100Z-K  SKA0300Z-K  SKA0500Z-K  SKA0500Z-K  Type of closure Sterilisation  Labelling  Temperature range Autoclavability  Physical resistance  Shelf life (before use)	Description  Ref(s)  Pot sizes:  50 ml / 100  100 ml / 300  300 ml / 500  500 ml/100  Conform to  93/42/EEC,  amendment  to ISO 1348  CE marking  CE 1639 (Clatissue for in  Manufacture  Product ass BS/EN/ISO 2  Dimensions and Volume  SKA0050Z-K  Inner pot  Outer pot  SKA0100Z-K  Inner pot  Outer Pot  SKA0300Z-K  Inner pot  Outer pot  SKA0500Z-K  Inner pot  Outer pot  Not suitable  Tamper-evic  Sterilisation  accordance  Labelling  Case, pack a  1:2016  Temperature range  -80° C to 75  Autoclavability  Not suitable  Physical resistance  Shelf life (before use)  Packs contemporator  Packs SKA0050Z-K  Inner pot  Outer pot  Not suitable  Packs SKA0050Z-K  Inner pot  Outer pot  Not suitable  Packs SKA0050Z-K  Inner pot  Outer pot  Not suitable  Packs SKA0050Z-K  Inner pot  Outer pot  Outer pot  Not suitable  Packs SKA0050Z-K  Inner pot  Outer pot  Outer pot  Outer pot  Not suitable  Packs SKA0050Z-K  Inner pot  Outer pot  Oute	Description   Freezable Tissue Storage   Form   Freezable Tissue Storage   Form   Freezable Tissue Storage   Form   Freezable Tissue Storage   Form   Form	Description	Description  Ref(s)  Pot sizes:  S0 ml / 100 ml  SKA00502-K  100 ml / 500 ml  SKA01002-K  300 ml / 500 ml  SKA05002-K  Conform to the relevant provisions of the EC of 93/42/EEC, dated 14th June 1993 and all their amendments. Annex V sterility aspects only. Not 150 13485:2016.  CE marking  CE 1639 (Class IIa medical device suitable for stissue for in vivo use)  Manufacture  Product assembled in class 7 cleanroom in acc 85/EN/ISO 14644-1:2015.  Dimensions and Volume    SKA0050Z-K   Inner pot   57   41.4   34.8   00.4   34.8   00.4   72.1   00.4   34.8   00.4   72.1   00.4   34.8   00.4   72.1   00.4   34.8   00.4   72.1   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4   00.4	Pot sizes: Ref:   50 ml / 100 ml   SKA0050Z-K   100 ml / 300 ml   SKA0100Z-K   300 ml / 500 ml   SKA0500Z-K   500 ml/1000 ml   500 ml		

				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.			
		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.			
		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	Storage conditions before packs opened		Temperature: 10°C to 35°C Relative Humidity: 20% to 80% Store in clean, dry conditions away from direct sunlight.				
18	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> <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 order to be used.</li> </ul>				
19	19 Product labels		mm wide x 40	ole Tissue Storage Kit ol: 50 ml   100 ml  50Z-K LOT 000000  1			
			mm wide x 40	ole Tissue Storage Kit 1: 100 ml   300 ml 00Z-K LOT 000000  1			

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

## Freezable Tissue Storage Kit Vol: 300 ml | 500 ml

REF SKA0300Z-K STERILE EO (1639)

LOT SAMPLE

FTK\_90x35\_v2

Eastern Road, Aldershot, UK. medfor.co.uk

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

Freezable Tissue Storage Kit Vol: 500 ml | 1000 ml

REF SKA0500Z-K STERILE EO 1 1 1 2 1639

LOT SAMPLE

FTK\_90x35\_v2

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Aldershot, UK.
medfor.co.uk