

Product name

Wrapped Containers, sterile R

STERILE R

Basic UDI-DI

506056603B1GAZI

GMDN code

63838 - General tissue specimen container IVD, no additive.

Product REFs

See table 1 below.

Intended purpose

Intended for general in-vitro use within the laboratory or as specimen receptacles.

Operational information

- To be used by persons suitably trained in the intended use of the device.

Storage before pack is opened

- Store in clean, dry conditions away from direct sunlight.
- Store at temperatures of 10° C to 35° C and RH of 20% to 80%.

Materials

See table 1 below.

Contraindications, complications and side effects

None known.



Warning—precautions



- Read instructions for use leaflet prior to use.
- For single use only, do not reuse as this can cause cross contamination.
- Check the expiry date on the label before use – do not use after the expiry date.
- Do not use if the package or product has been damaged or contaminated.
- Device is supplied sterile, so use device immediately after opening the pouch.
- Do not use containers or caps that have been left out of their pouches or where pouches have been left open as sterility will have been compromised.
- Outer carton - check sterilisation indicator label for colour. Red = sterilised, yellow = NOT STERILE.

Disposal

Dispose of used containers in contaminated waste disposal system or according to your local policy.

Serious incidents

Should a serious incident arise as a result of using the container, please report this immediately to the manufacturer and the Competent Authority where the device is being used.

Shelf life

- 35 months from date of manufacture, as printed on pouch.
- Use by the expiry date noted on the pouch label.

Table 1: Product REFs and Materials

Product REF	Material			
	Container	Cap	Pouch	
OWA0250D-K	PP	PP	Medical grade paper & PET/PE	
OWA0500D-K				
OWA0750D-K				
OWA1000D-K				
OWA2000D-K				
OWF0500E-K				
S114-K	PS	PS		
S240	PP	HDPE		
SQC0250D-J	PET	HDPE		
SQC0500D-J				
SSA0060D-K	PS	Metal		
SSA0060F-K				
SSA0100D-K				
SSA0100F-K				
SSA0250D-K				
SSA0250F-K				
SSE0150D-K				

Product REF	Material		
	Container	Cap	Pouch
SSE0150F-K	PS	Metal	Medical grade paper & PET/PE
TPA0035D-K	PP	PE	
TPA0055D-K			
TPA0125D-K			
TPE0035D-K			
TPE0055D-K			
TPE0055D-L10			
TPE0125D-K			
TPE0125D-L5			
TPE0180D-K			
TPF0055D-L5	PS	HDPE	
TPF0125D-L4			
UVB0030D-K			
UVB0030F-K	PP	HDPE	
WPC0700D-J			
WPC1250D-K			
WPE0300E-K			