

EU Declaration of Conformity (Directive 93/42/EEC)

MANUFACTURER		
Name of Company	Address	SRN
Medfor Products Ltd	Unit 2, Gresham Industrial Estate, Eastern Road, Aldershot, GU12 4YD, UK.	GB-MF-0000022996

AUTHORISED REPRESENTATIVE			
Name of Company	Address	SRN	Telephone / Email
Emergo Europe	Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands	NL-AR-000000116	+31.70.345.8570 emergoeurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	Basic UDI_DI	Product REFs
Plastic containers for the transit and storage of human organs and tissues prior to transplantation.	506056603MDDE6	See details in Table 1 attached.

Intended purpose	
For the transit and storage of human organs and tissues prior to transplantation by healthcare professionals.	
Risk Class	Conformity Assessment Route
Class IIa as per MDD 93/42/EEC Annex IX, Section III, Rule 2	Sterile products: MDD 93/42/EEC Annex V Non-sterile products: MDD 93/42/EEC
Statements	
Relevant Standards	
Medfor Products Ltd manufactures the devices according to the applicable requirements of the relevant harmonised standards listed in Table 2 attached.	

Medfor Products Ltd declares, under our sole responsibility, that the devices listed on the attached Device Schedule conform to the relevant provisions of the EU Council Directive 93/42/EEC, dated 14 June 1993 and the relevant amendments of 2007/47/EE, Annex V.

Medfor Products Ltd agrees to develop, implement and maintain a formally recognised Quality Management System to ensure continued adequacy and efficacy.

COMPANY REPRESENTATIVE /

PERSON RESPONSIBLE FOR REGULATORY COMPLIANCE : Rob Stephens

TITLE: Commercial Director

SIGNATURE: 

PLACE: Aldershot, UK

DATE: 15 January 2024



TABLE 1: DEVICE SCHEDULE

Sterility Type

Non-Sterile

REF	Description
S072	500ml 750ml White Tissue Storage Kit (autoclavable), non-sterile

Sterility Type

Irradiated - sterile

REF	Description
OWE0050D-K	50 ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE0125D-K	125 ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE0250D-K	250ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE0500D-K	500ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE0750D-K	750ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE1000D-K	1000ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
OWE2000D-K	2000ml White Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
PNC0025D-K	25 ml Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
PNC0250D-K	250 ml Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
PNC0500D-K	500 ml Tissue Storage Pot (1 PC/pack), double wrapped, sterile R [prev S348-K]
PNC1000D-K	1000 ml Tissue Storage Pot (1 PC/pack), double wrapped, sterile R
PNF0050D-K	50 ml Tissue Storage Pot - cap separate (1 PC/pack), double wrapped, sterile R
PNF0050D-K2	50 ml Tissue Storage Pot - cap separate (2 PCS/pack), double wrapped, sterile R
PNF0050D-K20	50 ml Tissue Storage Pot (20 PCS/pack), double wrapped, sterile R
PNF0050D-K4	50 ml Tissue Storage Pot (4 PCS/pack), double wrapped, sterile R
PNX0050D-K2	50 ml Tissue Storage Pot - with extra cap (2 PCS/pack), double wrapped, sterile R [prev S215-K]
S146-K	50 ml 100 ml White Freezable Tissue Storage Kit (10 PCS/pack), double wrapped, sterile R
S152-K	2000 ml White Tissue Storage Pot - cap wadded (1 PC/pack), double wrapped, sterile R.
S216-K	60 ml Eyeball Storage Pot (2 PCS/pack), double wrapped, sterile R
S224-J	250 ml Tissue Storage Pot (1 PC/pack), single wrapped, sterile R.
S296-K	500 ml 750 ml White Freezable Tissue Storage Kit - Theatre label (1 PC/pack), double wrapped, sterile R
S402-K	1250 ml 2000 ml White Freezable Tissue Storage Kit - blank label (1 PC/pack), double wrapped, sterile R
S631-K	Closure for 50 ml Tissue Storage Pot (5 PCS/pack), double wrapped, sterile R

Sterility Type

Ethylene Oxide - sterile

REF	Description
S227-K	300 ml 500 ml White Freezable Tissue Storage Kit - NBS label (1 PC/pack), double wrapped, sterile EO
S406-K	300ml 500ml White Freezable Tissue Storage Kit - push-on out. cap (1 PC/pack), double wrapped, sterile EO
SKA0050Z-K	50 ml 100 ml Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
SKA0100Z-K	100 ml 300 ml Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
SKA0300Z-K	300 ml 500 ml Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
SKA0500Z-K	500 ml 1000 ml Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
SPA0050Z-K	50 ml Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile EO
SPA0050Z-K5	50 ml Freezable Tissue Storage Pot (5 PCS/pack), double wrapped, sterile EO
SPA0100Z-K	100 ml Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile EO
SPA0100Z-K5	100 ml Freezable Tissue Storage Pot (5 PCS/pack), double wrapped, sterile EO
SPA0300Z-K	300 ml Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile EO
SPA0500Z-K	500 ml Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile EO
SPA1000Z-K	1000 ml Freezable Tissue Storage Pot (1 PC/pack), double wrapped, sterile EO
WKA0050Z-K	50 ml 100 ml White Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
WKA0100Z-K	100 ml 300 ml White Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO

WKA0300Z-K	300 ml 500 ml White Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
WKA0700Z-K	700 ml 1250 ml White Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO
WKC1250Z-K	1250 ml 2000 ml White Freezable Tissue Storage Kit (1 PC/pack), double wrapped, sterile EO

TABLE 2: RELEVANT STANDARDS

Applicable to all Products above:

Standard	Description
BS EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
BS EN ISO 14971:2019	Medical Devices - Application of Risk Management to Medical Devices
BS EN ISO 15223-1:2021	Medical Devices - Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements
BS EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
BS EN ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness.
BS EN ISO 10993-1:2020	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a Risk Management process

Applicable to gamma and EO sterilised products above:

Standard	Description
BS EN ISO 11138-1:2017	Sterilisation of health care products-Biological Indicators-Part1: General Requirements
BS EN ISO 11607-1:2020	Packaging for terminally sterilised medical devices. Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2020	Packaging for terminally sterilised medical devices. Validation requirements for forming, sealing and assembly processes

Applicable to gamma sterilised products only above:

Standard	Description
BS EN ISO 11137-1:2015	Sterilisation of health care products-Radiation-Part 1: Requirements for development, validation and routine control of a sterilisation process for medical devices
BS EN ISO 11137-2:2015	Sterilisation of health care products - Radiation - Part 2: Establishing the sterilization dose

Applicable to EO sterilised products only above:

Standard	Description
BS EN ISO 11135:2014	Sterilisation of health care products - Ethylene Oxide. Requirements for the development, validation and routine control of a sterilisation process for medical devices.