

UK Declaration of Conformity (Regulation MDR 2002)

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

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 UK MDR2002 Annex IX, Section III, Rule 2	Sterile products: UK MDR2002 Annex V Non-sterile products: UK MDR2002

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 UK MDR2002.

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.