



## DECLARATION OF CONFORMITY

Manufacturer	Medfor Products Limited Unit 2, Gresham Industrial Estate Eastern Road Aldershot, Hampshire GU12 4YD United Kingdom
Representative	Mr Rob Stephens, Commercial Director
Devices	Storage Containers and lids - as per attached Device Schedule
Notified Body	SGS Belgium NV SGS House Noorderlaan 87 2030 Antwerp Belgium
Notified Body Number	1639
EC Certificate number	GB19/964231
Classification	Class IIa
Classification Rule	MDD 93/42/EEC Annex IX, Section III, Rule 2
Conformity Assessment Route	MDD 93/42/EEC Annex V

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

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

Medfor Products Ltd manufactures according to the following harmonised standards:

Standard	Description
ISO 13485:2016/EN ISO 13485:2016	Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
ISO 15223-1:2016	Medical Devices - Symbols to be used with Medical Device Labels, Labelling and Information to be supplied – Part 1: General Requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
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.

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
ISO 11137-2:2015	Sterilisation of health care products-Radiation-Part 1: Establishing the sterilisation dose
ISO 11138:2006	Sterilisation of health care products-Biological Indicators-Part1: General Requirements
ISO 14644-1:2015	Cleanrooms and associated controlled environments. Classification of air cleanliness
ISO 10993-1:2009	Biological Evaluation of medical devices – Part 1: Evaluation and testing within a Risk Management process
EN ISO 11607-1:2009+A1:2014	Packaging for terminally sterilised medical devices. Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2006+A1:2014	Packaging for terminally sterilised medical devices. Validation requirements for forming, sealing and assembly processes



Signed .....  
Rob Stephens, Commercial Director

Date: 1 November 2019

## DEVICE SCHEDULE

OWE0125D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S248-J	Pot for transport / storage of human tissue
OWE0250D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S253-J	Pot for transport / storage of human tissue
OWE0500D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S296-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
OWE0750D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S348-K	Pot for transport / storage of human tissue
OWE1000D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S400-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
OWE2000D-K	Pot suitable for freezing to -80° C for transport / storage of human tissue	S401-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNA0500E-L	Pot for transport / storage of human tissue	S402-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNC0025D-K	Pot for transport / storage of human tissue	S403-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNC0250D-K	Pot for transport / storage of human tissue	S406-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNC1000D-K	Pot for transport / storage of human tissue	S411-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNF0050D-K	Pot for transport / storage of human tissue	S412-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNF0050D-K2	Kit for transport / storage of human tissue	S450-K	Pot suitable for freezing to -80° C for transport / storage of human tissue
PNF0050D-K20	Kit for transport / storage of human tissue	S600-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
PNF0050D-K4	Kit for transport / storage of human tissue	S610-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S072	Kit suitable for freezing to -80° C for transport / storage of human tissue	S631-K	Accessory for pot for transport / storage of human tissue
S146-K	Kit suitable for freezing to -80° C for transport / storage of human tissue	SKA0050Z-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S147-K	Kit suitable for freezing to -80° C for transport / storage of human tissue	SKA0100Z-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S148-K	Kit suitable for freezing to -80° C for transport / storage of human tissue	SKA0300Z-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S152-K	Pot for transport / storage of human tissue	SKA0500Z-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S212-J	Kit for transport / storage of human tissue	SKB0050Z-K	Kit suitable for freezing to -80° C for transport / storage of human tissue
S215-K	Kit for transport / storage of human tissue	SPA0050Z-K5	Pot suitable for freezing to -80° C for transport / storage of human tissue
S216-K	Kit for transport / storage of human tissue	SPA0100Z-K5	Pot suitable for freezing to -80° C for transport / storage of human tissue
S224-J	Pot for transport / storage of human tissue		
S227-K	Kit suitable for freezing to -80° C for transport / storage of human tissue		
S234-J	Kit for transport / storage of human tissue		
S238-K	Kit for transport / storage of human tissue		
S241-K	Kit for transport / storage of human tissue		
S242-K	Kit for transport / storage of human tissue		
S245-J	Pot suitable for freezing to -80° C for transport / storage of human tissue		