

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 samples for in vitro diagnostic testing	506056603IVDF8	See details in Table 1 attached.
Intended purpose		
Intended for general in-vitro use within the laboratory or as specimen receptacles.		
Risk Class	Conformity Assessment Route	
General	98/79/EC Annex III excluding section 6	
Statements		
The devices have no measuring function and are not reusable surgical instruments.		
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 Regulation MDR 2002 on in vitro diagnostic medical devices.

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

PLACE: Aldershot, UK

SIGNATURE: 

DATE: 13 September 2024



TABLE 1: DEVICE SCHEDULE

Sub-group	
Non-wrapped containers	
Sterility Type	
Non-Sterile	
REF	Description
SSA0060A	60ml clear PS jar fitted with flow-seal metal screw cap
SSA0100A	100ml clear PS jar fitted with flow-seal metal screw cap
SSB0250A	250ml clear PS jar fitted with wadded metal screw cap
SSB0250B	250ml clear PS jar fitted with wadded metal screw cap, plain label
SSC0060A	60ml clear PS jar fitted with white HDPE screw cap
SSC0060B	60ml clear PS jar fitted with white HDPE screw cap, plain label
SSC0060W	60ml clear PS jar fitted with white HDPE screw cap, blank label
SSD0100A	100ml clear PS jar fitted with white PP screw cap (EPE wad)
SSD0100B	100ml clear PS jar fitted with white PP screw cap (EPE wad), plain label
SSE0150A	150ml clear PS jar fitted with flow-seal metal screw cap
UVA0030A	30ml clear PS universal tube fitted with HDPE screw cap
UVA0030B	30ml clear PS universal tube fitted with HDPE screw cap, plain label
Sterility Type	
Sterile R	
REF	Description
SSA0060D	60ml clear PS jar fitted with flow-seal metal screw cap, sterile R
SSA0060E	60ml clear PS jar fitted with flow-seal metal screw cap, plain label, sterile R
SSA0060F	60ml clear polystyrene jar fitted with flow-seal metal screw cap, hospital label, sterile R
SSA0060K	60ml clear PS jar fitted with flow-seal metal screw cap, sterile seal, sterile R
SSA0100D	100ml clear PS jar fitted with flow-seal metal screw cap, sterile R
SSA0100E	100ml clear PS jar fitted with flow-seal metal screw cap, plain label, sterile R
SSA0100M	100ml clear PS jar fitted with flow-seal metal screw cap, plain label and sterile seal, sterile R
SSB0250D	250ml clear PS jar fitted with wadded metal screw cap, sterile R
SSB0250E	250ml clear PS jar fitted with wadded metal screw cap, plain label, sterile R
SSB0250F	250ml clear PS jar fitted with wadded metal screw cap, hospital label, sterile R
SSC0060D	60ml clear PS jar fitted with white HDPE screw cap, sterile R
SSC0060E	60ml clear PS jar fitted with white HDPE screw cap, plain label, sterile R
SSC0060F	60ml clear PS jar fitted with white HDPE screw cap, hospital label, sterile R
SSD0100D	100ml clear PS jar fitted with white PP screw cap (EPE wad), sterile R
SSD0100E	100ml clear PS jar fitted with white PP screw cap (EPE wad), plain label, sterile R
SSD0100M	100ml clear PS jar fitted with white PP screw cap (EPE wad), sterile seal, sterile R
SSE0150D	150ml clear PS jar fitted with flow-seal metal screw cap, sterile R
SSE0150E	150ml clear PS jar fitted with flow-seal metal screw cap, plain label, sterile R
UVA0030D	30ml clear PS universal tube fitted with HDPE screw cap, sterile R
UVA0030E	30ml clear PS universal tube fitted with HDPE screw cap, plain label, sterile R
UVA0030F	30ml clear PS universal tube fitted with HDPE screw cap, hospital label, sterile R

Sub-group	
Wrapped containers	
Sterility Type	
Sterile R	
REF	Description
OWA0250D-K	250ml white PP jar fitted with white PP screw cap (EPE wad) (1 PC/pack), double wrapped, sterile R
OWA0500D-K	500ml white PP jar fitted with white PP screw cap (EPE wad) (1 PC/pack), double wrapped, sterile R
OWA0750D-K	750ml white PP jar fitted with white PP screw cap (EPE wad) (1 PC/pack), double wrapped, sterile R
OWA1000D-K	1000ml white PP jar fitted with white PP screw cap (EPE wad) (1 PC/pack), double wrapped, sterile R
OWA2000D-K	2000ml white PP jar fitted with white PP screw cap (EPE wad) (1 PC/pack), double wrapped, sterile R
OWF0500E-K	500ml opaque white PP jar separate with white PP screw cap (1 PC/pack), plain label double wrapped, sterile R
S114-K	90mm unvented petri dishes double wrapped (1 PC/pack), sterile R
S240	25ml polypropylene tube fitted with yellow screw caps (1 PC/pack), labelled, double wrapped, sterile R
SQC0250D-J	250ml clear PET square bottle with GREEN HDPE tamper-evident screw cap (1 PC/pack), single wrapped, sterile R
SQC0500D-J	500ml clear PET square bottle separate with GREEN HDPE tamper-evident screw cap (1 PC/pack), single wrapped, sterile R
SSA0060D-K	60ml clear PS jar fitted with flow-seal metal screw cap (1 PC/pack), double wrapped, sterile R
SSA0060F-K	60ml clear PS jar fitted with flow-seal metal screw cap, hospital label (1 PC/pack), double wrapped, sterile R
SSA0100D-K	100ml clear PS jar fitted with flow-seal metal screw cap (1 PC/pack), double wrapped, sterile R
SSA0100F-K	100ml clear PS jar fitted with flow-seal metal screw cap, hospital label (1 PC/pack), double wrapped, sterile R
SSB0250D-K	250ml clear PS jar fitted with wadded metal screw cap (1 PC/pack), double wrapped, sterile R
SSB0250F-K	250ml clear PS jar fitted with wadded metal screw cap, hospital label (1 PC/pack), double wrapped, sterile R
SSE0150D-K	150ml clear PS jar fitted with flow-seal metal screw cap (1 PC/pack), double wrapped, sterile R
SSE0150F-K	150ml clear PS jar fitted with flow-seal metal screw cap, hospital label (1 PC/pack), double wrapped, sterile R
TPA0035D-K	35ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped, Sterile R
TPA0055D-K	55ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped, Sterile R
TPA0125D-K	125ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped, Sterile R
TPA0180D-K	180ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped, Sterile R
TPE0035D-K	35ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped (+ client label), Sterile R
TPE0055D-K	55ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped (+ client label), Sterile R
TPE0055D-L10	55ml transparent PP jar with fitted PE screw cap (10 inner-packs of 1 PC/pack), tripple wrapped, Sterile R
TPE0125D-K	125ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped (+ client label), Sterile R
TPE0125D-L5	125ml transparent PP jar with fitted PE screw cap (5 inner-packs of 1 PC/pack), tripple wrapped, Sterile R
TPE0180D-K	180ml transparent PP jar with fitted PE screw cap (1 PC/pack), double wrapped (+ client label), Sterile R
TPF0055D-L5	55 ml transparent PP jar with fitted PE screw cap (5 inner-packs of 2 PCS/pack), tripple wrapped, Sterile R
TPF0125D-L4	125 ml transparent PP jar with fitted PE screw cap (4 inner-packs of 2 PCS/pack), triple wrapped, Sterile R
UVB0030D-K	30ml clear PS universal tube with fitted HDPE screw cap (1 PC/pack), double wrapped, Sterile R
UVB0030F-K	30ml clear PS universal tube with fitted HDPE screw cap, hospital label (1 PC/pack), double wrapped, Sterile R
WPC0700D-J	700ml white PP jar with loosely fitted white HDPE tamper-evident screw cap (1 PC/pack), single wrapped, sterile R
WPC1250D-K	1250ml white PP jar fitted with white HDPE tamper-evident screw cap (1 PC/pack), double wrapped, sterile R
WPE0300E-K	300ml white PP jar with separate white HDPE tamper-evident screw cap, plain label (1 PC/pack), double wrapped, sterile R

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 ISO 20417:2021	Information supplied by the manufacturer of medical devices
BS EN ISO 6717:2021	In vitro diagnostic medical devices. Single use receptacles for the collection of specimens, other than blood, from humans

Applicable to gamma sterilised products 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