TECHNICAL INFORMATION SHEET

Urine Collection Container: PCAN01

Product Catalogue Number / REF

PCAN01

Product Name / Description

Safe2Pcanter

Product Second Description

Urine Collection Container

Intended Use

Hand-held Urine Collection Container, single use.
Not to be used where a sterile environment is required.

Product General Description

The Urine Collection Container is a flat-packed, single use, non-sterile medical device, which is intended to be directly urinated into by a patient.
This device enables users to self-collect urine sample in a non-clinical environment. Health or social care professionals may also assist with the collection of urine samples in a clinical or non-clinical setting. Collected urine sample may be used for testing, except microbiological testing, when sterile specimen receptacle is required.

The wide aperture makes it easier to collect the sample, reducing spillages, and the square design of the cup provides a natural and accurate pouring spout for decanting into the final urine storage or transport container.



Product Specification

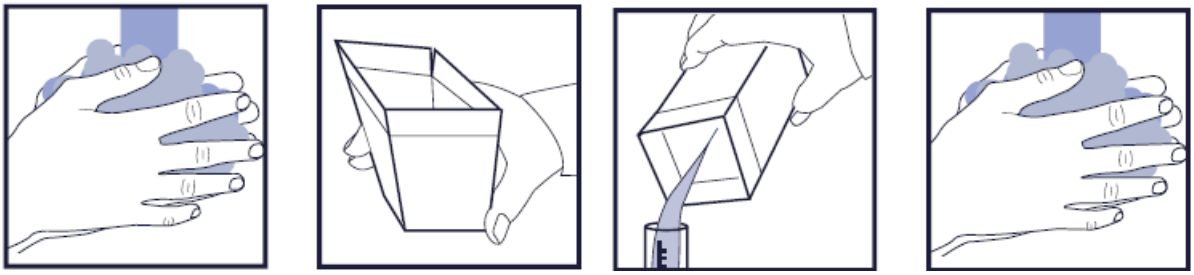
Material of rigid outer:	Paperboard with PE coating
Material of inner bag:	Natural LDPE – 70% virgin + 30% recycled from post-consumer waste, side weld polythene bag
Size flat:	L102 x H122mm
Size opened (3D shape):	L51 x W51 x H122mm
Capacity of opened:	Max 200ml
1 unit weight:	10g
1000 unit case weight :	10kg 87g
1000 unit case size:	L410 x W305 x H305mm
Product Storage:	Keep it dry before use Keep away from sunlight Store at room temperature (15-25 degrees C)
Sterility:	Non-sterile
Shelf-life:	3 years from manufacturer

Contraindication

Urine Collection Container is not sterile, so can only be used for general testing.
Urine Collection Container is not suitable for urine samples transportation.

Instructions For Use

Provided in pictorials:



Packaging & Labelling Information

Flat-packed 1000 per box, with information provided by manufacturer leaflet (with translations to IT, FR, DE, ES languages) placed on top.

All labelling complies with the requirements of the EU MDR 2017/745 and UK MDR 2002, and includes CE and UKCA marking. Information provided:

On the device:

- Manufacturer name
- Manufacturer address
- Product Catalogue Number (PCN) / REF
- Product Name
- Non-Sterile symbol
- UKCA marking
- Authorised representative details
- CE marking
- Medical Device symbol
- Do not re-use symbols
- Lot number
- Do not use if damaged symbol
- Keep it dry symbol
- Storage temperature requirement
- Device artwork details and issue date
- Instructions in languages: EN, IT, FR, DE, ES
- Instructions for Use (pictorials)
- UDI-PI (AI)

On the outer packaging:

- Manufacturer name
- Manufacturer address
- Product Catalogue Number (PCN) / REF
- Product Name
- Non-Sterile symbol
- UKCA marking
- Authorised representative details
- CE marking
- Medical Device symbol
- Do not re-use symbols
- Lot number
- Do not use if damaged symbol
- Keep it dry symbol
- Storage temperature requirement
- Keep away from sunlight symbol
- Manufacture date
- Consult Instructions for Use symbol
- Expiry
- UDI-PI (AI)
- Quantity
- Customer order details

TECHNICAL INFORMATION SHEET

Urine Collection Container: PCAN01

Compliance

Regulation:	EU Medical Devices Regulation (EU MD) 2017/745	UK Medical Devices Regulation 2002	US Code of Federal Regulations Title 21
	EMDN: A99	GMDN: 40955	GMDN: 40955
Classification:	Class 1 non invasive, Rule 1	Class 1, Rule 1	Class 1
Basic UDI	50567516MDTF0027P4		

Manufacturer Information

Legal Manufacturer:

REAL Digital International Ltd
2 Queensway
Croydon
CR0 4BD
United Kingdom

Standards:

ISO 13485
ISO 9001
ISO 14001
ISO 27001

EU Authorised Representative

Casus Europe B.V.
Lange Viestraat 2b
3511 BK Utrecht
The Netherlands
Tel: +31 30 899 3946
Email: EURep@casusconsulting.com

United States Agent Information

AJW Technology Consultants, Inc.
11705 Boyette Road, #503
Riverview, Florida, 33569,
UNITED STATES
Phone: 813 - 6452855 -104

References

Not applicable.

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