



SYNTESYS



Cert. N.7111/2



Cert. N.6574/2



SYNTESYS S.R.L. UNIPERSONALE

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TECHNICAL SHEET

Page 1 Rev. 01 Date: 01/10/2021

PRODUCT CODE: 331193

Description:

**POLYPROPYLENE URINE CONTAINER 200 ML
 WITH SEPARATED WHITE SCREW CAP**



Specifications and Dimensions:

CONTAINER

CAP

Diameter.: 60 mm
 Height: 96 mm
 Total Volume: 200 ml

Standard white cap

Graduations:

10-30-50-70-90-110-130-150-170 ML

Microbiological Status:

Not sterile

Packaging:

Single

Sub-packages

Package

Specific packaging

/

Inner protection bag

400 pcs

Double wave corrugated cardboard size 600x400x660 mm
 Gross Weight: kg. 9
 Volume: 0,88 m³

Intended use:

Collection of biologic sample (urine), for subsequent treatment-analyse chemical, clinical and/or microbiological.
 The product is aimed at professional in biomedical laboratories for analysis.

Storage and conservation:

The storage and conservation of the product for a long time must take place at one temperature included in a range from + 5 to + 25 ° C, in a dry place.

Quality System applied:

UNI EN ISO 9001: 2008 ICIM certificate n. 4264/3 issued by ICIM S.p.a. in date 18/01/2016
 UNI EN 13485: 2012 ICIM certificate n. 4265/3 issued by ICIM S.p.a. on 18/01/2016
 CE: Quality assurance system by issuing the Declaration of CE Conformity after the preparation of the technical-production files according to EEC Directive 98/79 / EC available to the competent authority.
 UNI CEI EN ISO 15223-1 Symbols to be used in the labels of the device doctor, in the labeling and in the information that must be provided
 UNI EN 1041 Information supplied by the manufacturer with medical devices
 UNI EN 14971 Application of risk management to medical devices

Certification of materials:

POLYPROPYLENE the container and POLYETHYLENE the cap

A-toxic materials, soft, translucent, flexible and impact resistant. Good resistance to chemical solvent.
 The raw materials used are a-toxic for food and medical certificate in accordance with European regulations and FDA (USA) force

Method of disposal:

Before use, they are to be considered non-hazardous waste to be disposed of pursuant to of Legislative Decree 156/06 and subsequent amendments
 After use they are potentially infected medical waste: CER 18 01 03 * waste which must be collected and disposed of, applying special precautions for avoid infections

Manufacturer:

ROLL S.R.L.

SYNTESYS S.R.L.
 UNIPERSONALE
 Il Legale Rappresentante
 Rinaldo Ruggero