

SYNTESYS S.R.L. UNIPERSONALE

VIA G. GALILEI, 10/3 - 35037 Z.I. SELVE DI TEOLO (PD) TEL. •39 049 9903866 R.A. FAX •39 049 9903867 C.F./P.I./N.REG.IMP. PADOVA 03573950288 REA PD-320123 - CAP.SOC. 20.700,00€ E-MAIL INFO@SYNTESYS.IT PEC POSTA@PEC.SYNTESYS.IT



| TECHNICAL SHEET | | | | | |
|--|-------------------------|------------------|----------------|--|--|
| Page 1 | Rev. 00 Date 30/09/2021 | | | | |
| PRODUCT CODE: 331200 | | | | | |
| Description: | | | | | |
| STERILE POLYPROPYLENE URINE CONTAINER 200 ML WITH RED SCREW CAP INDIVIDUALLY WRAPPED AND LABEL | | | | | |
| Specifics and dimensions: | | | | | |
| CONTAINER | | | CAP | | |
| Mouth diameter: 60 mm Height: 96 mm Volume: 200 ml | | Standard red cap | | | |
| Graduations: | | | | | |
| Internal slightly raised MI 10-30-50-70-90-110-130-150-170 | | | | | |
| Microbiological status: | | | | | |
| By irradiation, in accordance with the standards: | | | | | |
| UNI EN 556-1 Requirements for medical devices bearing the indication sterile, | | | | | |
| UNI EN ISO 11137-1 Sterilization of health products - Radiation - Part 1 | | | | | |
| UNI EN ISO 11737-2 Microbiological methods - Sterility tests performed in course of validation of a sterilization process. | | | | | |
| Packaging: | | | | | |
| Single | Under Packaging | Packagir | ng | Specifics packaging | |
| Yes | / | 250 pieces | | Double wave corrugated cardboard size: 600x400x365 mm Gross Weight: kg. 4,6 Volume: 0,088 m ³ | |
| Intended use: | | | | | |
| Collection of biologic liquid (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. | | | | | |
| Certification of materials: | | | | | |
| POLYPROPYLENE the container and POLYETHYLENE the cap | | | | | |
| Atoxic materials, soft, transluced, flexible and impact resistant. Good resistance to chemical solvent. | | | | | |
| The raw materials used are atoxic for food and medical certificate in accordance with European regulations and FDA (USA) force. | | | | | |
| Method of disposal: | | | | | |
| For correct disposal, refer to the relevant national and local regulations of medical waste in force in the country of use of the product. | | | | | |
| Disposal BEFORE their use (ex: expired or deteriorated): | | | | | |
| | Classification | | | CER 15 01 02 or 20 01 39 | |
| | | | AFTER their us | | |
| Classification: special hazardous waste CER 18 01 03 * or 18 02 02 * | | | | | |
| Regulatory standard: CE Marked: CE mark and issuing the Declaration of Conformity as a result of the technical dossier in accordance of EEC Directive 98/79/CE (D.Lgs. n. 332/2000) | | | | | |
| and to the competent authority to ensure that the manufacturing process meets the requirements of quality assurance of production. | | | | | |
| Manufacturer: | | | | | |
| ROLL S.R.L. | | | | | |

