„DINOPOL" SPÓŁKA Z O.O.
UL. ODOLANOWSKA 91
63-400 OSTRÓW WIELKOPOLSKI, PL
NIP: 622-266-42-12

Kidney bowl MED – 05

Dimensions +/- 5 mm (l x w x h):	245x115x50 mm
Max capacity:	600 ml
Working capacity:	300 ml
Resistance to permeation:	4h
Temperature resistance:	35 °C
Units per package:	300

1. **CLASSIFICATION:** Medical Device – According to rule I of the classification specified in Appendix VIII of Regulation (EU) 2017/745 of the European Parliament and of the European Council of 5 April 2017 on medical devices, amendments to Directive 2001/83 / EC, Regulation (EC) No. 178 / 2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC (Text with EEA relevance.), and in accordance with § 4. item 2.1, Minister of Health Regulation of 05 November 2010 on the methods of classification of medical devices, the product, as a non-invasive medical device, has been classified as **class I (RULE 1)** medical device, and the procedure of the product's compliance with basic requirements has been carried out in pursuance with Appendix 2 No. VII to the Minister of Heath Regulation of 17 February 2016 on basic requirements and procedures of assessing compliance of medical devices.

2. **PURPOSE:** Disposable dish for used tools, injection needles, accessories for oral examination of patients, used swabs, pads, vomit and other toxic waste from doctor's offices.

3. **DISPOSAL:** Sanitary dishes, and their content, are disposed of in a macerator, and then waste is emptied into drains so as to prevent epidemiological and ecological risks.

4. **MATERIAL:** The goods are made of paper pulp.

5. **RESISTANCE TO PERMEATION:** The medical devices resist permeation of liquid substances for up to 4 hrs.

6. **RISK ANALYSIS:** On the basis of the performed analysis of risk it has been confirmed that if the medical device is used in pursuance with its intended purpose, no risk has been identified. Solutions adopted by Dinopol Sp. z o.o. while designing, as well as in the phase of construction of the medical device comply with safety regulations. Our medical devices meet performance parameters provided for by the manufacturer, and they are designed, manufactured, and packed appropriately for medical products. The manner in which the devices are designed, manufactured, and packed prevents deterioration of their performance parameters when used in pursuance with their intended purpose, or as a result of shipping or storing.

7. **STORING CONDITIONS:** Packages shall be stored in dry rooms. Avoid direct contact with water, contamination or rodents.

8. **STORING TIME:** Packages shall not be stored longer than necessary (36 months from the production date).

9. **CE MARKING:** CE marking can be found on every medical device, and on every bulk package.

10. **STATUTORY REQUIREMENT:** "Dinopol" Sp. z o.o. has fulfilled statutory requirement consisting of registering the medical devices in the Office for Registration of Medical Products, Medical Devices and Biocidal Products.

11. The manufacturer applies the Quality and Environmental Management System PN-EN ISO 9001: 2015, PN-EN ISO 14001: 2015, which has been confirmed by a Certificate issued by the TUV NORD Certification Body and Documented FSC CoC Product Origin Control System, which was confirmed by a Certificate issued by the Certification Body SGS Polska Sp. z o.o.