



DECLARATION OF CONFORMITY



„DINOPOL” SPÓŁKA Z O.O.

UL. ODOLANOWSKA 91, 63-400 OSTRÓW WIELKOPOLSKI

UL. FABRYCZNA 5, RACZYCE, 63-430 ODOLANÓW

NIP: 622-266-42-12, REGON:300746859

Tel. 62 736 20 99, fax 62 738 07 58,

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The manufacturer of medical, single-use product,
made of paper pulp:

KIDNEY BOWL

MED-05

GMN (Basic UDI-DI) -5907784409MED-05DB

declares under his sole responsibility that the above mentioned products are

in conformity with:


- 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.) (MDR)

CLASSIFICATION: 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.), the product, as a non-invasive medical device, has been classified as **class I (RULE 1)** medical device.

The conformity assessment procedure was carried out on the basis of the technical documentation prepared in accordance with Appendix II and III of the above-mentioned regulation.

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

PURPOSE OF THE MEDICAL DEVICE: 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.

Place and date	Issued by (name, surname, position, signature)
Ostrów Wielkopolski, 01.09.2022	WICEPREZES ZARZĄDU  Monika Nowicka-Zmuda

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