

EU DECLARATION OF CONFORMITY

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Manufacturer: **"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY**
46 Boremłowska Street, 04-347 Warsaw, Poland

We apply the certified
Quality Management System
in accordance
with the standards: PN-EN ISO 9001:2015, PN-EN ISO 13485:2016

Product name: **Laboratory centrifuge MPW-55**

The aforementioned product is in conformity with the following EU regulations and directives:

- **2017/746 (IVDR)** REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- **2011/65/UE (RoHS 2)** DIRECTIVE 2011/65/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

Intended purpose: The product is a benchtop laboratory centrifuge specifically intended by the manufacturer for in vitro diagnostic (IVD) procedures. It is used for the separation of mixtures, suspensions, body fluids into components of different density under the influence of centrifugal force.

Risk class: **Class A (in accordance with Annex VIII, rule 5)**

The assessment of the conformity of the device has been carried out in accordance with Article 48(10) of Regulation (EU) 2017/746.


Wojciech Anisiewicz
Vice-President of the Management Board




Łukasz Satański
President of the Management Board