MPW®
MED. INSTRUMENTS

CE

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 Boremlowska Street, 04-347 Warsaw, Poland**
The Quality Management System complies with the standards:	PN-EN ISO 9001:2015, PN-EN ISO 13485:2016
SRN:	PL-MF-000032831
Device name:	**Laboratory centrifuge MPW-351e** (with the accessory indicated in the operating instructions provided with the centrifuge)
BASIC UDI-DI:	590538636-IVD-CEN-008-6J
Catalogue numbers:	10351e/2-56 10351e/1-56 10351e/1-56/100 10351e/1-56/110 10351e/1-56/127

The aforementioned device 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, including the changes published prior to the date of this declaration.
2011/65/EU (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, including the changes published prior to the date of this declaration.
Intended purpose:	The device is intended for the separation of the mixtures of the liquid substances derived from the human body, including blood, urine, and other body fluids, and for the preparation of the samples intended for further in vitro diagnostics procedures.
Risk class:	Class A (in accordance with the rule 5 of Annex VIII of Regulation (EU) 2017/746).

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

Wojciech Anisiewicz
Vice-President of the Management Board

Łukasz Sałański
President of the Management Board

Warsaw, 23 January 2023

no. 10.351e.16o.en