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-56** (with the accessory indicated in the operating instructions provided with the centrifuge)
BASIC UDI-DI:	590538636-IVD-CEN-016-6H
Catalogue numbers:	10056/12-56

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. 10.056.16o.en

Office for Registration
of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, 02-222 Warsaw, Poland; Phone +48 22 492-11-00, fax +48 22 492-11-09
NIP 521-32-14-182 REGON 015249601

Warszawa, 01 -08- 2023

CERTIFICATE OF FREE SALE No. 539/2023

President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products based on Article 55 of the Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostics medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117 z 5.5.2017, p. 176) pursuant to art. 30 of the Act of April 7, 2022 on medical devices (Journal of Laws of 2022, items 974) in connection with the application for a certificate of free sale made by the

"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY
(*applicant for certificate of free sale*)

certifies that the in vitro diagnostics medical device listed below:

Name of the device	Type
Laboratory centrifuge MPW-56	MPW-56
Notified body certificate number	Not applicable
Basic UDI-DI code	590538636-IVD-CEN-016-6H

manufactured by :

"MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY
ul. Boremlowska 46, 04-347 Warszawa, Poland
(*identification of the manufacturer*)

on the basis of the statement of the manufacturer is CE marked at the sole responsibility of the manufacturer. The medical device CE marked in conformity with the Regulation (EU) 2017/746 of the European Parliament and of the Council can be placed on the market and put into service in the European Union. Export of the product is not prohibited.

URZĘDU REJESTRACJI PRODUKTÓW MEDYCZNYCH I PRODUKTÓW BIOBÓJCZYCH PREZES WYRÓBÓW * 2 *

President of the Office

On behalf of the President
Vice-President for Medical Devices

Sebastian Migdalski