MPW®
MED. INSTRUMENTS

EU DECLARATION OF CONFORMITY

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

Manufacturer:	**"MPW MED. INTRUMENTS" SPÓŁDZIELNIA PRACY** **46 Boremlowska 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:	**Refrigerated laboratory centrifuge MPW-352R**

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.

Digitally signed by Cobzari-Țurcan Rodica
Date: 2023.05.02 10:22:07 EEST
Reason: MoldSign Signature
Location: Moldova

Wojciech Anisiewicz
Vice-President of the Management Board

Łukasz Sałański
President of the Management Board

Warsaw, 26 May 2022

no. 10.352R.16b.pl