MPW®
MED. INSTRUMENTS

no. DoC.16610.en_rev.1

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
Product name:	CYTO set — The set includes: 16611 CYTO base and insert, 16614 Microscope slide, 16616 Filter card with Ø 9,5 mm hole, 16617 Filter card with Ø 12,5 mm hole, 15123 Supernatant tube 2,2 ml.
Basic UDI-DI:	590538636-IVD-CEN-019-6S
Catalogue number:	16610

The aforementioned product is in conformity with the following EU regulation:

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
Intended purpose:	CYTO set is an accessory for in vitro diagnostics medical devices, that is, the laboratory centrifuges specifically intended by the manufacturer for in vitro diagnostic (IVD) procedures. The set is used for the preparation and storage of the biological fluids intended for further in vitro diagnostics.
Risk class:	Class A (in accordance with the rule 5 of Annex VIII of Regulation (EU) 2017/746).

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

Warsaw, 23 January 2023

Halina Ducka
Plenipotentiary of the Management Board

Łukasz Sałański
President of the Management Board