"MPW MED. INSTRUMENTS"
SPÓŁDZIELNIA PRACY
04-347 Warsaw, 46 Boremlowska St.
applies the Quality Management System
in accordance with PN-EN ISO 9001:2015 and PN-EN
ISO 13485:2016

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ISO 9001 ISO 13485

MANUFACTURER'S STATEMENT

On behalf of "MPW MED. INSTRUMENTS" SPÓŁDZIELNIA PRACY we ensure that we make our best efforts to meet the current requirements under the applicable regulations.

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 entered into force 20 days after publication in the Official Journal of the European Union, so this occurred in 2017. We would like to point out that until today the EU has not published the full list of harmonized standards to Regulation 2017/746, hence as of today we are unable to conduct a proper conformity assessment of the products manufactured by us.

To sum up, currently we can declare that all our new products introduced for the first time on the market for the first time after May 26, 2022, will comply with Regulation 2017/746, while with regard to our devices already on the market based on compliance with DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of October 27, 1998 on in vitro diagnostic medical devices for in vitro diagnosis, they will be recertified (assessed for compliance) with Regulation 2017/746 successively until May 26, 2025.

Z-ca PREZESA ZARZĄDU
Wojciech Anisiewicz

PREZES ZARZĄDU
mgr Łukasz Sałański

Warsaw, November 30, 2021

no. 10.000.01_21.pl