

DECLARATION OF CONFORMITY

Product name: **Laboratory centrifuge MPW M-DIAGNOSTIC**

Product type: **Laboratory centrifuge**

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

Product classification on the basis of the Directive 98/79/EC: Non classified to list A or B and not for self-testing.

Product complies with the requirements:

• **Directive 98/79/EC (IVD), including the requirements of harmonized standards:**

EN 15223-1:2016

EN ISO 18113-3:2011

EN 13612:2002

EN 61326-2-6:2006

EN 13612:2002/AC:2002

EN 61010-2-101:2002

EN 13975:2003

EN 62304:2006

EN ISO 14971:2012

EN 62304:2006/AC:2008

EN ISO 18113-1:2011

EN 62366:2008

• **selected harmonized standards of Directive 2014/35/UE (LVD):**

EN 61010-1:2010

EN 61010-2-020:2006

• **directive 2014/30/UE (EMC).**

"MPW MED. INSTRUMENTS"

SPÓŁDZIELNIA PRACY

Warsaw, 46 Boremłowska Street

applies Quality Management System in line with

PN-EN ISO 9001:2015, PN-EN ISO 13485:2016

Certifying authority:

"MPW MED. INSTRUMENTS"

SPÓŁDZIELNIA PRACY

w Warszawie

Członek Zarządu

Wojciech Anisiewicz

PREZES ZARZADU

mgr Łukasz Satański



Warsaw, 2018.09.15

no. 10.2MD.02.en