

DECLARATION OF CONFORMITY



**PTAK
WARSAW
EXPO**

MANUFACTURER: PTAK WARSAW EXPO SP. Z O.O.
ADRESS: AL. KATOWICKA 62, 05-830 NADARZYN
PRODUCT NAME: DISPOSABLE MEDICAL MASK
TYPE: II, IIR
CLASS: MEDICAL DEVICE CLASS I, RULE I
PACKAGING: 10/20/50 PIECES



CONFORMITY ASSESSMENT:

WE HEREBY DECLARE UNDER OUR SOLE RESPONSIBILITY THAT THE CLASS 1 MEDICAL DEVICE – SINGLE-USE MEDICAL MASK – COMPLIES WITH THE REQUIREMENTS OF THE LAW OF 20 MAY 2010 ON MEDICAL DEVICES (OJ OF 2020, ITEM 186, AS AMENDED) WHICH IMPLEMENTS THE PROVISIONS OF DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES.

THE CONFORMITY ASSESSMENT OF THE MENTIONED PRODUCT WAS CARRIED OUT IN ACCORDANCE WITH ANNEX NUMBER 7 TO THE ORDINANCE OF THE MINISTER OF HEALTH OF 17 FEBRUARY 2016 RELATING TO THE ESSENTIAL REQUIREMENTS AND PROCEDURES FOR THE EVALUATION OF MEDICAL DEVICES (OJ OF 2016, ITEM 211).

I HEREBY CONFIRM THAT THE CIOP TESTS SUBMITTED FOR MASKS ARE RELATED TO THOSE DESCRIBED IN THE DECLARATION OF CONFORMITY AND ARE MADE OF THE SAME MATERIAL AS THE MASKS TESTED.

**THE PRODUCT COMPLIES
WITH THE STANDARD:**

PN-EN 14683:2019 + AC

Manufacturer - PTAK Warsaw Expo Sp. z o.o.

PREZES ZARZĄDU Wiceprezes Zarządu

Tomasz Szypuła

Kazimierz Ćwikła

signature

Place and date of issue: Nadarzyn, 22.03.2021

MADE
IN POLAND

**PTAK
WARSAW
EXPO**

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