

CERTIFIED TRANSLATION FROM POLISH

Katarzyna Kaczmarczyk, Certified Translator of the English Language no. TP/740/05
Record no. 1525/11/2020 • 17 November 2020 • Page 1 of 1

PROF. J. NOFER OCCUPATIONAL MEDICINE INSTITUTE

INSTITUTE

**LABORATORY FOR RESEARCH ON MEDICINAL
AND VETERINARY PRODUCTS IN THE GMP QUALITY SYSTEM**

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Customer (under Contract no. ZLB/45/2020):

TW PLAST Sp. z o.o.

05-500 Piaseczno, ul. Puławska 38
Tax Id. No. (NIP): 9372722562, Business Reg. No. (REGON): 383776873
National Court Register (KRS) No.: 0000792916, www.twplast.pl

SKIN IRRITATION TEST CERTIFICATE
STANDARD: PN-EN ISO 10993-10:2015-05

Medical device	Series number	Date of manufacture
Type I, II, IIR medical masks	105250920	25/09/2020

METHODOLOGY:

Standard: PN- EN ISO 10993-10:2015-02

DESIRED RESULT:

In dermal, single and repeated, closed exposure:

- the medical device does not irritate the skin locally;
- cumulative irritation index: 0.00;
- non-irritating medical device.

RESULT



NON-IRRITATING FOR THE SKIN



IRRITATING FOR THE SKIN

PERMITTED BY THE LOCAL ETHICAL COMMITTEE FOR EXPERIMENTS ON ANIMALS IN ŁÓDŹ,
RESOLUTION NO. 29/ŁB 30/2016 OF 20 JUNE 2016 (ASSESSMENT OF LOCAL SKIN IRRITATION IN THE
GMP QUALITY SYSTEM)

CONCLUSION:

Medical device - type I, II, IIR medical masks (series: 105250920, production date: 25/09/2020,
manufacturer: TW Plast Sp. z o. o.):

- should not pose a risk of local irritation to humans;
- the cumulative irritation index was 0.00;
- the test result meets the requirements of PN-EN ISO 10993-10:2015-02.

Researchers:

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Łódź, 2 November 2020
WHO Collaborating Center

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I, Katarzyna Kaczmarczyk, Certified Translator and Interpreter of the English Language, entered onto the list of
certified translators and interpreters kept by the Minister of Justice under no. TP/740/05, hereby approve
conformity of the present translation with a scan of the original document in the Polish language.

