

CERTIFIED TRANSLATION FROM POLISH

*Katarzyna Kaczmarczyk, Certified Translator of the English Language no. TP/740/05
Record no. 985/07/2020 • 20 July 2020 • Page 1 of 1*

[logo]

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Al. Jerozolimskie 181C, 02-222 Warszawa, Poland, T: +48 22 492-11-00, F: +48 22 492-11-09,
Tax Id. No. (NIP): 521-32-14-182, Business Reg. No. (REGON): 015249601

Warsaw, 26 May 2020

DEPARTMENT OF INFORMATION ON MEDICAL DEVICES

DIM.IMB.4141.72.2020.DW.1

To:

TW PLAST Sp. z o.o.
ul. Puławska 38
05-500 Piaseczno, Poland

In reference to the application of 18 May 2020 (date of receipt by the Office: 21 May 2020), the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products is sending the enclosed certificate.

Enclosures:

1. Original CERTIFICATE NO. 76/2020

Copies to:

- 1.1 copy - addressee
- 2.1 copy - on files

[illegible signature and stamp:]

For the President

DIRECTOR of the Department of Information on Medical Devices
Elżbieta Maciejewska

END OF TRANSLATION

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 source document in the Polish language.



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Tax Id. No. (NIP): 521-32-14-182, Business Reg. No. (REGON): 015249601

Warsaw, 26-05-2020

CERTIFICATE NO. 76/2020

To:

TW PLAST Sp. z o.o.
ul. Puławska 38
05-500 Piaseczno, Poland

Pursuant to Article 217 § 2.2 in connection with Art. 218 § 1 of the Administrative Procedure Code Act of 14 June 1960 (Journal of Laws of 2020, Item 256), after considering the application dated 18 May 2020:

the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

certifies that:

upon analyzing the data from the submissions and notifications referred to in Art. 64 Sec. 1 of the Act on Medical Devices of 20 May 2010 (Journal of Laws of 2020, Item 186), a submission for the following product is hereby confirmed:

PRAESIDIUM

Alternative name: THREE-PLY MEDICAL MASKS

Type: TYPE II, NON-STERILE, VERSION WITH ELASTIC STRAPS

Manufacturer: TW PLAST Sp. z o.o., ul. Puławska 38, 05-500 Piaseczno, Poland

The President of the Office informs that this certificate is to confirm the receipt of the submission, and at the same time it does not confirm whether the submission is complete and correct, and it is not a decision on whether the said products are medical devices or not within the meaning of the Act on Medical Devices of 20 May 2010 (Journal of Laws of 2020, Item 186) or whether they meet the requirements of the said Act.

[illegible signature and stamp:]

For the President

DIRECTOR of the Department of Information on Medical Devices

Elżbieta Maciejewska

Page 1-2 of 2

END OF TRANSLATION

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 source document in the Polish language.

