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**TARCHOMIŃSKIE ZAKŁADY  
FARMACEUTYCZNE „POLFA”  
SPÓŁKA AKCYJNA**  
ul. Aleksandra Fleminga 2, 03-176 Warszawa

Warszawa dn. 2020/10/21

## DECLARATION OF CONFORMITY

Tarchomińskie Zakłady Farmaceutyczne „Polfa” Spółka Akcyjna as a manufacturer of:

### **TZF II R MEDICAL MASK**

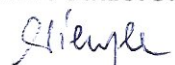
declare that the **TZF II R MEDICAL MASK** is classified as a medical device class I (according to Council Directive 93/42/EEC), and meet the standard requirements according to:

EN 14683+AC:2019 “ Medical face masks – Requirements and test methods” for type IIR.

**TZF II R MEDICAL MASK** conforms to the essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices; Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007, and also to the following standards:

1. ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes;
2. EN ISO 15223-1:2016 – Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements;
3. EN 1041:2008+A1:2013 - Information supplied by the manufacturer of medical devices.

QUALITY DIRECTOR

  
Gabriela Wiergowska