

KASTER



EC DECLARATION OF CONFORMITY No. 1 / KAS / 2020

MANUFACTURER: Pracownia Krawiecka KASTER Katarzyna Pytel
ul. 3 Maja 70A, 34-240 Jordanów
NIP: 7351450991, REGON: 490747624

MEDICAL PRODUCT: Disposable 3-layer mask type IIR / Disposable Face Mask
3 layers, type IIR produced according to EN 14683: 2019+AC:2019-09
with BFE filtration efficiency ≥ 95 . Class of component – I.

I declare with full responsibility that the above medical device:

It has been classified in class I module A

And it complies with the requirements of Council Directive 93/42 / EEC of June 14, 1995 concerning medical devices, amended by Directive 2007/47 / EC of the European Parliament and of the Council of September 8, 2007 and harmonized standards with it:

1. PN-EN 14683 + AC Medical masks. Requirements and test methods.
2. PN-EN ISO 14971: 2012 Application of risk management to medical devices.
3. PN-EN 1041 + A1: 2013-12 Information provided by medical device manufacturers.
4. PN-EN ISO 15223-1: 2012 Symbols for use on labels of medical devices, their marking and information provided with them.

And the Act of May 20, 2010 on medical devices (Journal of Laws 2010 No. 107 Item 679) and the Regulation of the Minister of Health of January 12, 2011 on the essential requirements and procedures for assessing the conformity of medical devices (Journal of Laws 2011 No. 16, item 74).

The organization declares that the procedure for assessing the conformity of medical devices has been carried out in accordance with Annex VII to the Regulation of the Minister of Health of 12 January 2011 on the essential requirements and procedures for assessing the conformity of medical devices.

This EC declaration of conformity, together with the technical documentation, is the basis for marking the product with the CE mark.

Date of issue: 01.06.2020

Declaration issued by: Katarzyna Pytel

Place of issue: Jordanów

Signature:

KASTER

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