



EC DECLARATION OF CONFORMITY

issued on the basis of the provisions of Section 13, Paragraph 2 of Act No. 22/1997 Coll., on technical requirements for products, as amended, in conjunction with Act No. 268/2014 Coll., on medical devices and Government Regulation No. 54/2015 Coll., on technical requirements for medical devices, as amended (hereinafter referred to as "Government Regulation No. 54/2015 Coll.).

Manufacturer: Balerina-Czech, s.r.o.

Address: Přestavická 1447, 295 01 Mnichovo Hradiště, Česká republika

CIN: 49550578

hereby confirms that for the medical device:

Disposable 3-layers Face Mask Balerina

a conformity assessment was performed in accordance with Annex No. 7 to Government Regulation No. 54/2015 Coll.,

and declares,

that the properties of the above-mentioned medical device meet all the essential requirements set out in Government Regulation No. 54/2015 Coll. and that the medical device is safe, effective and suitable to provide health care during its normal use. The manufacturer further declares that he has taken measures to ensure the conformity of all packages of the above-mentioned medical device placed on the market with the essential requirements and technical documentation of the manufacturer.

Intended purpose: The intended purpose of the face mask is to reduce the risk of transmission of infection, especially from the user to the environment.

In Mnichovo Hradiště on 2nd of September, 2020

Balerina - Czech, s.r.o.

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Petr Prokůpek

Executive

Balerina-Czech, s.r.o.