GEVORKYAN, s.r.o.
Powder Metallurgy Plant
Invoice and Plant Address:
Továrenská 504
976 31 Vlkanová
Slovak Republic

CE Declaration of Conformity

and Product Parameters
for the Medical Device **class I**

Based on the Council Directive 93/42/EEC of 14 June 1993 concerning "medical devices" and Commission Recommendation (EU) 2020/403 of 13 March 2020 on "conformity assessment and market surveillance procedures within the context of the COVID-19 threat and the Commission Guidance on "conformity assessment procedures for protective equipment" of 27.03.2020 for the implementation of Regulation (EU) 2016/425 and the Council Directive No. 93/42/ EEC and the Regulation (EU) 2017/745, and in accordance with the government decree No. 582/2008 Coll. determining the details of technical requirements and procedures for the conformity assessment of medical devices, and Act of the National Council of the Slovak republic No. 362/2011 Coll on medicines and medical devices, as amended.

The producer declares the conformity of product: "**Medical mask**",
Verified according to EN 14683:2019+AC:2019 (E) – medical mask **Type II**
Model: Mask Mia/Smart/Industry
Year of production: 2020
Name of producer: Gevorkyan s.r.o.
Address: Továrenská 504, Vlkanová 976 31, SLOVAKIA
ID: 36017205
Tax ID: 2020085606
www.gevorkyan.sk

Description: **medical mask for multiple use with replaceable filtering elements**

The solution is subject of the protection of patent application **Patent PP50020-2020** and **Utility model PUV50032-2020.** The product is safe for its intended use, and measures have been adopted to ensure the compliance of product with documentation, the requirements of the Government Decree of the Slovak Republic No. 404/2007 Coll. on general safety of products that relate to the product and with the requirements of technical regulations.
The producer declares that the filtering element demonstrates the antibacterial effectiveness
95.7 %
According to ASTM E 2149-13a Test Report No. 84/2020 VÚTCH-CHEMITEX 23/3/2020.

The producer declares that the filtering element demonstrates the bacterial filtering effectiveness (BFA)
98.2 %
Test report No. 005/2020 STU in Bratislava, ÚTACHTM 1/7/2020.

In accordance with the standard EN ISO 109931:2009, the producer declares that all the materials used in product are health friendly based on the below stated output documents:

Certificate No. 00025/118/2020 on health due to skin contact according to STN 80 055, dated 8 April, 2020 issued by "Výskumný ústav chemických vlákien, a.s." (Research Institute of Chemical Fibres), Štúrova 2, 059 21 Svit

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In accordance with the standard EN ISO 10993-1:2009, the producer declares that all the materials used in product are health friendly based on the below stated output documents:
Certificate No. 00025/118/2020 on health due to skin contact according to STN 80 055, dated 8 April, 2020 issued by "Výskumný ústav chemických vlákien, a.s." (Research Institute of Chemical Fibres), Štúrova 2,059 21 Svit.
Certificate R000003226 Pharmaceutical declaration on health due to skin contact according to EC No 1935/2004, EC No 2023/2006, EU No 10/2011, dated 01.10.2019 issued by DMS Engineering Plastics BV, Urmonderbaan 22, Geleen, the Netherlands
Certificate R000009595 EU FOOD CONTACT declaration on health according to US Pharmacopeia Pastic Class VI, dated 11.11.2019 issued by DMS Engineering Plastics BV, Urmonderbaan 22, Geleen, the Netherlands.
Certificate R000012450 USA FOOD CONTACT declaration, dated 19.12.2019, issued by DMS Engineering Plastics BV, Urmonderbaan 22, Geleen, the Netherlands.

The conformity of product is ensured by the producer during production process based on:
Internal documentation of quality: PK_01 Integrated Manual of Quality and Environmental Engineering, version D 08/06/2017.
Certificates of Quality Management System:
ISO 9001: 2015 Reg. No. 12 100 52698 TMS issued by TÜV SUD - DAkkS D-ZM-14143-01-00
STN EN ISO 14001: 2016 Reg. No. E 0181-3 issued by TÜV SUD - SNAS Reg. No. 153/R-006
IATF 16949 Reg. No. 12 111 52698 TMS issued by TÜV SUD.

All the documents including the technical documentation are archived by the manufacturer.
This Declaration of Conformity relates exclusively to the product in the state in which it was placed on the market**,** and excludes components which are added and/or operations carried out subsequently by the final user.

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SK 976 31 Vlkanová, Slovakia

FDA

U. S. Food and Drug Administration
Establishment Owner Operator number:
10077368

Declaration No.: RG381/2020

EN 14683:2019+AC:2019 (E)
ASTM E 2149-13a
STN 80 055
EC No 1935/2004, EC No2023/2006, EU No 10/2011

Intended use: medical mask for multiple use with replaceable filtering elements

Vlkanová, 17.09.2020

Signature: Dipl. Ing. Artur Gevorkyan
Chief Executive Officer

TÜV SÜD IATF 16949 TÜV SÜD ISO 9001 TÜV SÜD ISO 14001 EPMA MEMBER 2020