

Declaration of Conformity

1. **Product:** Medical face mask
2. **Reference number:** PM04 (Attachment no. 1)
3. **Trade name:** PARTA Medica
4. **Manufacturer:** TNS SERVIS s.r.o., K Teplinám 619
763 15 Slušovice, Czech Republic
SRN: CZ-MF-000004832
GMN 859420754PM04KF

5. **This declaration is issued under the sole responsibility of the manufacturer.**

The manufacturer declares that the above mentioned medical device "Medical face mask" complies with Act No. 268/2014 Coll., on medical devices, and Government Decree No. 54/2015 Coll., on technical requirements for medical devices. The medical device is suitable, safe and effective for its intended purpose.

6. **Subject of declaration:**

Product: Medical face mask

Description and intended use: Disposable four-layer mask made of non-woven fabric with a nanofiltration membrane designed as a protection/prevention of infections spread by droplet transmission.

Product classification: **Class I, non-sterile, without a measuring function** (Rule 1 according to Government Decree No. 54/2015 Coll., Annex 9, Chapter III, Article 3)

Declaration of conformity procedure: according to Annex 7 Government Decree No 54/2015 Coll., as amended

7. **The above described subject of the declaration is in compliance with the applicable harmonisation legislation of the European Union:**

Council Directive No. 93/42/EEC, as amended
Act No. 268/2014 Coll., as amended
Government Decree No. 54/2015 Coll., as amended

8. **References to the applicable harmonised standards that have been used or to other technical specifications on the basis of which conformity is declared:**

ČSN EN 14 683 + AC Medical face masks – Requirements and test methods
ČSN EN ISO 11737-1 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
ČSN EN ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ČSN EN ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ČSN EN ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
ČSN EN ISO 14971 – Medical devices – Application of risk management to medical devices
ČSN EN ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
ČSN EN 1041 + A1 Information supplied by the manufacturer of medical devices
ČSN EN ISO 9001 Quality management systems – Requirements

Slušovice, 24. 5. 2021


Ing. Jiří Klouda
CEO

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Attachment no. 1

Kód/Code	Název/Title
PM043205	Zdravotnická obličejová maska – modrá, folie 5 ks (nanomembrána)
PM043305	Zdravotnická obličejová maska - žlutá, folie 5 ks (nanomembrána)
PM043405	Zdravotnická obličejová maska - růžová, folie 5 ks (nanomembrána)
PM043505	Zdravotnická obličejová maska - černá, folie 5 ks (nanomembrána)