EU Declaration of Conformity

1. **Product:** Medical face mask
2. **Reference number:** PM02 (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 859420754PM02KB

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 Regulation (EU) 2017/745 of the European Parliament and of the Council, on medical devices, and Act No. 89/2021 Coll., on 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 three-layer mask made of non-woven fabric 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 Regulation (EU) 2017/745 of the European Parliament and of the Council
Declaration of conformity procedure:	according to Annex II, III Regulation (EU) 2017/745 of the European Parliament and of the Council

7. **The above described subject of the declaration is in compliance with the applicable harmonisation legislation of the European Union:**
   Regulation (EU) 2017/745 of the European Parliament and of the Council
   Act No. 89/2021 Coll., as amended
   Act No. 90/2016 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 14 683:2020 + AC:2020 Medical face masks – Requirements and test methods
   ČSN EN ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products
   ČSN EN ISO 10993-1:2021 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
   ČSN EN ISO 10993-5:2010 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
   ČSN EN ISO 10993-10:2014 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
   ČSN EN ISO 14971:2020 Medical devices – Application of risk management to medical devices
   ISO/TR 24971:2020 Medical devices - Guidance on the application of ISO14971
   ČSN EN ISO 15223-1:2017 Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
   ČSN EN ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
   ČSN EN ISO 13485 ed.2:2016 Medical devices - Quality management systems – Requirements for regulatory proposes

Slusovice 19. 01. 2022

Ing. Jiří Klouda
CEO

EU Declaration of Conformity

Attachment no. 1

Kód	Title	UDI-DI (GTIN A)
PM023205	Medical Face Mask - blue, Typ II, folie 5 pcs (meltblown)	8594207540015
PM023250	Medical Face Mask - blue, Typ II, box 50 pcs (meltblown)	8594207540022
PM023105	Medical Face Mask - white, Typ II, folie 5 pcs (meltblown)	8594207540077
PM023305	Medical Face Mask - yellow, Typ II, folie 5 pcs (meltblown)	8594207540084
PM023405	Medical Face Mask - pink, Typ II, folie 5 pcs (meltblown)	8594207540091
PM023505	Medical Face Mask - black, Typ II, folie 5 pcs (meltblown)	8594207540107
PM023201	Medical Face Mask - blue, Typ II, folie 1 pc (meltblown)	8594207540114
PM023101	Medical Face Mask - white, Typ II, folie 1 pc (meltblown)	8594207540121
PM023301	Medical Face Mask -yellow, Typ II, fólie 1 pc (meltblown)	8594207540138
PM023401	Medical Face Mask - pink, Typ II, fólie 1 pc (meltblown)	8594207540145
PM023501	Medical Face Mask - black, Typ II, fólie 1 pc (meltblown)	8594207540152