

EU DECLARATION OF CONFORMITY

Manufacturer:

SRN: CZ-MF-000014366

Holík International s.r.o.

Za Dvorem 612,
763 14, Zlín 12,
Czech Republic

Branch office:

Šedesátá 7046,
760 01, Zlín,
Czech Republic

This declaration of conformity is issued under the sole responsibility of the manufacturer Holík International s.r.o..

Product identification:

Surgical Face Mask M8001

Basic UDI-DI: 859406007002GB

0745760934713 M8001_001 White, Box 50pcs
0745760934706 M8001_101 Blue, Box 50pcs
0745760934744 M8001_011 White anti-fog, Box 50pcs
0745760934720 M8001_101 Blue anti-fog, Box 50pcs
0745760934799 M8001_002 White, Bag 10pcs
0745110765646 M8001_003 White, Bag 5pcs
0745760934775 M8001_102 Blue, Bag 10pcs
0745760934782 M8001_103 Blue, Bag 5pcs
0745110765653 M8001_122 Blue anti-fog, Bag 10pcs
0745110765660 M8001_123 Blue anti-fog, Bag 5pcs

Intended use:

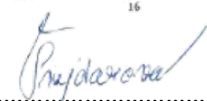
Surgical Face Mask M8001 is intended to reduce the risk of spread of infections, particularly from the user to the surroundings and to protect the wearer against splashes of potentially contaminated liquids.

Surgical Face Mask M8001 complies with the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices and was classified as medical device - risk class 1. The product fulfils all requirements of the harmonized standard ČSN EN 14683:2019+AC:2020: *Medical face masks – Requirements and test methods*. The product meets the requirements for the Type IIR. The mask is in conformity with the Test Report Ref. No. 2020TM4576, which was issued on the 29th September 2020 and with the Test Report ref. No 2020TM5522, which was issued on the 3rd December 2020 by the Notified Body No. 0161 – AITEX („Textile Industry Research Association“).

This Declaration of Conformity is available on the website www.holik-international.com.

In Zlín 12, 12th November 2021

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