

EU Declaration of conformity

pursuant to the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR), Article 19 and Annex IV.

Manufacturer: AV Medical CZ Ltd., Dobronická 1257, 148 00 Praha 4, Czech Republic, IČ: 26836530
SRN: CZ-MF-000002391
EMDN: D99

Trade name of the medical device: Multi-layers decontamination antibacterial sticky mats.

Variants of the medical device (differ in dimensions, color, number of sheets/layers):

size 60x40cm, 30-layers, blue; size 90x45cm, 30-layers, blue; size 60x76cm, 30-layers, blue; size 115x45cm, 30-layers, blue; size 90x60cm, 30-layers, blue; size 115x60cm, 30-layers, blue; size 114x66cm, 30-layers, blue; size 91x91cm, 30-layers, blue; size 115x90cm, 30-layers, blue; size 152x91cm, 30-layers, blue; size 60x40cm, 30-layers, white; size 90x45cm, 30-layers, white; size 60x76cm, 30-layers, white; size 90x60cm, 30-layers, white; size 115x60cm, 30-layers, white; size 114x66cm, 30-layers, white; size 91x91cm, 30-layers, white; size 115x90cm, 30-layers, white; size 152x91cm, 30-layers, white; size 90x45cm, 30-layers, gray; size 115x45cm, 30-layers, gray; dimension 90x60cm, 30-layers, gray; size 115x60cm, 30-layers, gray; size 114x66cm, 30-layers, gray; size 115x90cm, 30-layers, gray; size 115x45cm, 30-layers, green; size 115x60cm, 30-layers, green; size 115x90cm, 30-layers, green; size 115x45cm, 30-layers, red; size 115x45cm, 30-layers, yellow; size 115x60cm, 30-layers, red; size 115x60, 30-layers, yellow; size 90x4cm, 40-layers, blue; size 115x45cm, 40-layers, blue; size 115x60cm, 40-layers, blue; size 115x90cm, 40-layers, blue; size 90x45cm, 40-layers, white; size 115x45cm, 40-layers, white; size 115x60cm, 40-layers, white; size 115x90cm, 40-layers, white; size 90x45cm, 60-layers, blue; size 90x45cm, 60-layers, white; size 90x45cm, 60-layers, gray; size 115x45cm, 60-layers, blue; dimension 115x45cm, 60-layers, white; size 115x45cm, 60-layers, gray; size 60x90cm, 60-layers, blue; size 60x90cm, 60-layers, white; size 115x60cm, 60-layers, blue; size 115x60cm, 60-layers, white; size 115x60cm, 60-layers, gray; size 114x66cm, 60-layers, blue; size 114x66cm, 60-layers, white; size 114x66cm, 60-layers, gray; size 115x90cm, 60-layers, blue; size 115x90cm, 60-layers, white; size 115x90cm, 60-layers, gray.

Intended purpose of use: Removal of dirt and bacterial contamination from the wheels of medical devices and from the soles of shoes at the entrances to zones with high environmental cleanliness requirements.

Product basic UDI-DI according to Part C of MDR Annex VI: 859417198STICKYMATSFXX

Health risk rate/risk class according to Annex VIII MDR, rule 1: I / non-sterile, without measuring

Conformity assessment procedure based on risk class: Annexes II and III of the MDR.

We declare on our sole responsibility that the product complies with the requirements of the MDR that apply to it and is safe, effective and suitable under the conditions of normal use for the intended purpose of use and the user.

Place & date of issue, Prague: 7.03.2023

 **AV MEDICAL**

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