

Declaration of Conformity

issued in accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices



PATRON Bohemia a.s.
Ceskolipska 3419, 27601 Melnik, Czech Republic

Name of AP/MD:

TOM 5, stroller for children with special needs

Basic UDI-DI (GMN):

85912460T5YYYYYYY0000006C

Reference number/code:

T5YYYYYYY000000

Classification (Annex VIII):

Class I (non-invasive)

EMDN code:

< Y122703 >

ISO classification:

< 12-27-07 >

Assistive product/medical device (AP/MD) in the means of foldable multipurpose stroller for children and young adults with special needs. Assistive product/medical device in the means of wheeled mobility device, intended to transport a seated occupant (children, young adult), who has impaired mobility.

Assistive product/medical device trade name/names: TOM 5, TOM 5 Streeter, TOM 5 Clipper, TOM 5 Xcountry (abbrev.: TOM5, TOM5-ST, TOM5-CP, TOM5-XC)

Manufacturer declares:

- there has been provided conformity assessment to verify the conformity of above described product with the provisions of the Regulation (EU) 2017/745.
- product meets all the appropriate health and safety EU-requirements
- the use of product in usual conditions and in accordance to the information for use and manufacturer advices is safe for the determined kind of use
- there is a bearer of responsibility, that all the manufactured products comply to all the technical documentation and products essential requirements as stated.
- there is implemented and maintained appropriate system to keep series in conformity with this regulation, certified quality management systems: EN ISO 9001, EN ISO 13485
- all the technical documentation is located in the residence of manufacturer
- above-mentioned product complies with following principal standards and regulations:

ČSN EN ISO 9999:2022, ČSN EN ISO 21856:2023, ČSN EN 12183:2023
ISO 7176, ČSN EN ISO 14971, ČSN EN ISO 10993-1, ISO 16840-10, ČSN EN 1021-2, ČSN EN ISO 20471, ČSN 41 1109, ČSN 41 1343, ČSN EN 573-3, ČSN EN 755-2

The manufacturer hereby to declare, under his sole responsibility, that the product specified above confirms to the required provisions of the Regulation (EU) 2017/745.
Declared in Melnik on 01/02/2023.

Ing. Jiri Kotik
R&D Executive Manager

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