

DECLARATION OF CONFORMITY

Document 02/2020

Manufacturer:

GTM MOBIL MT T WALISIEWICZ Sp.K.
Dorodna 16, 03-195 Warsaw, Poland

Declares medical device:

Manual wheelchair model: GTM1

CE marked products are medical devices of class I, rule 1, in accordance with classification criteria from Appendix No. 9 of Medical Directive of European Union MDD 93/42/EEC and meet the essential requirements from Appendix No. 1 of this Directive.

Conformity assessment was conducted on the basis of Appendix No. 7 of the Medical Directive of the European Union MDD 93/42/EEC.

Products meet the requirements of the Act from 20th of May 2010 on medical devices and the Decree of the Minister of Health of Poland from 12th of January 2011 on basic requirements for various purposes medical devices.

Product meet the requirements of the common standard of the European Union:

- EN 1041+A1:2013-12
- EN ISO 14971:2012
- EN 12183:2014
- EN ISO 15223-1:2012

Warsaw, 2020-01-13



.....

Tomasz Walisiewicz, co-owner

GTM-MOBIL M-T
T. Walisiewicz Sp. Komandytowa
ul. Dorodna 16, 03-195 Warszawa
REGON: 147177279, NIP: 524-27-68-598

DECLARATION OF CONFORMITY

Document 01/2020

Manufacturer:

GTM MOBIL MT T WALISIEWICZ Sp.K.
Dorodna 16, 03-195 Warsaw, Poland

Declares medical device:

Manual wheelchair model: GTM MUSTANG

CE marked products are medical devices of class I, rule 1, in accordance with classification criteria from Appendix No. 9 of Medical Directive of European Union MDD 93/42/EEC and meet the essential requirements from Appendix No. 1 of this Directive.

Conformity assessment was conducted on the basis of Appendix No. 7 of the Medical Directive of the European Union MDD 93/42/EEC.

Products meet the requirements of the Act from 20th of May 2010 on medical devices and the Decree of the Minister of Health of Poland from 12th of January 2011 on basic requirements for various purposes medical devices.

Product meet the requirements of the common standard of the European Union:

- EN 1041+A1:2013-12
- EN ISO 14971:2012
- EN 12183:2014
- EN ISO 15223-1:2012

Warsaw, 2020-01-13


.....
Tomasz Walisiewicz, co-owner
GTM-MOBIL
T. Walisiewicz Sp. Komandytowa
ul. Dorodna 16, 03-195 Warszawa
REGON: 147177279, NIP: 524-27-68-598

DECLARATION OF CONFORMITY

Document 03/2020

Manufacturer:

GTM MOBIL MT T WALISIEWICZ Sp.K.
Dorodna 16, 03-195 Warsaw, Poland

Declares medical device:

Manual wheelchair model: GTM JAGUAR

CE marked products are medical devices of class I, rule 1, in accordance with classification criteria from Appendix No. 9 of Medical Directive of European Union MDD 93/42/EEC and meet the essential requirements from Appendix No. 1 of this Directive.

Conformity assessment was conducted on the basis of Appendix No. 7 of the Medical Directive of the European Union MDD 93/42/EEC.

Products meet the requirements of the Act from 20th of May 2010 on medical devices and the Decree of the Minister of Health of Poland from 12th of January 2011 on basic requirements for various purposes medical devices.

Product meet the requirements of the common standard of the European Union:

- EN 1041+A1:2013-12
- EN ISO 14971:2012
- EN 12183:2014
- EN ISO 15223-1:2012

Warsaw, 2020-01-13


.....

Tomasz Walisiewicz, co-owner

GTM-MOBIL M-T
T. Walisiewicz Sp. Komandytowa
ul. Dorodna 16, 03-195 Warszawa
REGON: 147177279, NIP: 524-27-68-573