EC DECLARATION OF CONFORMITY

No. **DZ/MD/09-00/03**

CE **2274**

1. Name of medical device:

CATHETER SYRINGES

2. Product variants:

50 (60) ml
100 ml

3. Manufacturer:

Przedsiębiorstwo Produkcyjne MARGOMED Stanisław Margol
ul. Plewińskiego 16, 20-270 Lublin, Poland
tel./fax +48 81 7452300, +48 81 7439633
www.margomed.com

4. Product description:

Three-part syringe with catheter tip is used for aspiration of liquids and making flush-ings. For single use only, sterile, non toxic, non pyrogenic. Sterilized by ethylene oxide. Guarantee period 3 years from production date.

Reference documents:

The product has been classified according to Act of Parliament dtd 20.05.2010 "about medical devices".
On the basis of the Medical Devices Directive 93/42/EEC, it has been classified in class I.

Medical Device Directive 93/42/EEC as amended by directive 2007/47/EC

PN-EN ISO 9001:2015-10	Quality management systems. Requirements
PN-EN ISO 13485:2016-04	Medical devices – Quality management systems. Requirements for regulatory purpose
PN-EN ISO 7886-1:2018-07	Sterile hypodermic syringes for single use — Part 1: Syringes for manual use
PN-EN ISO 10993-1:2010	Biological evaluation of medical devices.
PN EN ISO 11135-1:2014-08	Sterilization of health-care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
PN-EN ISO 80369-7:2017-08	Small-bore connectors for liquids and gases in healthcare applications – Part 7: Connectors for intravascular or hypodermic applications
PN-EN 15223-1:2017-02	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
PN-EN 1041:2013-12	Information supplied by the manufacturer of medical devices
PN-EN ISO 11607-1:2017-12	Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems
PN-EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates

6. Notified body:

The conformity assessment has been carried out by notified body.

TÜV NORD Polska Sp. z o.o.
ul. Mickiewicza 29, 40-085 KATOWICE / Poland
Notified Body No. 2274

7. Manufacturer declaration:

We declare with full responsibility that our product, to whom refers this declaration, fulfills the documents listed above.

Lublin, 05.06.2020

DYREKTOR
mgr inż. Stanisław Margol