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Warszawa, 15.07.2020

# CE DECLARATION OF CONFORMITY

ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski, ul. Zawiślańska 43, 03-068 Warszawa, acting as Manufacturer according to MDD Directive 93/42/EEC, and according to Medical Devices Act from 20 May 2010 (Dz. U. z 2020 r. poz. 186.) implementing MDD Directive at the territory of Poland, herein declares that:

**Rollator: AT51031, AT51034, AT51035, AT51036**

have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

The assessment of conformity procedure has been held according to Annex VII of MDD Directive 93/42/EEC, and according to Annex VII of Medical Devices Essential Requirements Regulation from 17 February 2016 ( Dz. U. z 2016, poz.211). including modifications of the above regulation, implementing MDD Directive at the territory of Poland.

The above mentioned devices comply with all applicable requirements of Annex I of MDD Directive 93/42/EEC, and according to Annex I of Medical Devices Essential Requirements Regulation from 17 February 2016 ( Dz. U. z 2016, poz.211). including modifications of the above regulation, implementing MDD Directive at the territory of Poland.

Applied standards: EN ISO 14971, EN 1041, EN ISO 15223-1, EN 12182, EN ISO 13485:2003, EN ISO 9001:2008.

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