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Warszawa, 25.04.2019

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 2015 r. poz. 876, z późn. zm.) implementing MDD Directive at the territory of Poland, herein declares that:

Rollator: AT51111, AT51112, AT51113

Ambona rollator AT51114

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. nr 16 poz. 74), 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. nr 16 poz. 74), 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.

Andrzej Tarnkowski
President

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