ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski
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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:

Telescoping Rom Knee AT53001

Telescoping Rom Knee Brace AT53002

Rigid orthosis for shank and foot AT53003, AT53004, AT53005, AT53006, AT53008

Telescoping Rom Elbow Brace AT53009

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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Warszawa, 14.09.2017

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:

Rollators: CA820G; CA861R; CA871G; CA881T; CA880

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 12 January 2011 (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 12 January 2011 (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.

We, ANTAR Sp. J. I. Groniecka- Tarnkowska, A. Tarnkowski herein declare, that **the maximum user weight for the above mentioned products is 120 kg.**

Andrzej Tarnkowski
President

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