ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski
z siedzibą w Warszawie, ul. Zawiślańska 43, 03-068 Warszawa
Tel.: +48 22 518 36 00; Fax: +48 22 518 36 30; E-mail: antar@antar.net

Warszawa, 2014-05-06

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. nr 107, poz. 649) implementing MDD Directive at the territory of Poland, herein declares that:

ROLLATORS: AT02008; AT02009; AT02010

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 15223-1; EN-11199-1; EN ISO 13485:2003; EN ISO 9001:2008

Andrzej Tarnkowski
President

"ANTAR" Sp. Jawna
Irena Groniecka-Tarnkowska
Andrzej Tarnkowski
03-068 Warszawa, ul. Zawiślańska 43
tel.: 0-22 518 36 00, fax: 0-22 518 36 30
NIP: 524-21-23-915 0-22 518 36 31