

Warszawa, 25.04.2019

CE DECLARATION OF CONFORMITY

ANTAR Sp. J. I. Groniecka-Tarnowska, A. Tarnowski, ul. Zawisłańska 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:

Orthopedic pillows: AT03001, AT03002

Lumbar cushion: AT03003, AT03004

Travel orthopedic pillow: AT03005

Seating cushion: AT03006

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

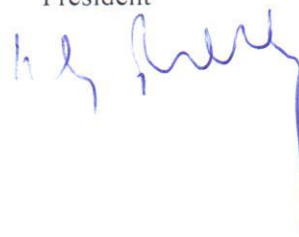
The assessment of conformity procedure has been held according to Annex VII of MDD Directive 93/42/EEC, and according to Annex VII of Medical Devices Essential Requirements Regulation from 17 February 2016 (Dz. U. nr 16 poz. 74), including modifications of the above regulation, implementing MDD Directive 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 Tarnowski

President



„ANTAR” Sp. Jawna
Irena Groniecka-Tarnowska
Andrzej Tarnowski
03-068 Warszawa, ul. Zawisłańska 43
tel.: 0 22 518 36 00 fax: 0 22 518 36 30
NIP: 524-21-23-915 0 22 518 36 31

Warszawa, 2013-07-19

CE DECLARATION OF CONFORMITY

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

ORTHOPEDIC PILLOWS: AT03001; AT03002
LUMBAR CUSHION: AT03003; AT03004
TRAVEL ORTHOPEDIC PILLOW: AT03005
SEATING CUSHION: AT03006

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 ISO 13485:2003, EN ISO 9001:2008

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

Andrzej Tarnkowski
President



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:

Cervical collar AT53029

Knee orthosis AT53035

Rigid cervical collar AT53036

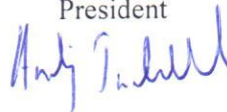
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

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



„ANTAR” Sp. Jawna
Irene 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

Warszawa, 25.04.2019

CE DECLARATION OF CONFORMITY

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

Knee brace AT04101, AT04102, AT04103, AT04104

Ankle orthosis AT04205, AT04206

Wrist Orthosis AT04301, AT04302

Torso orthoses AT04505, AT04507, AT04508

Lumbosacral spine orthoses AT04506

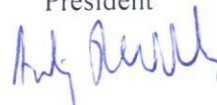
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

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



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

Warszawa, 25.04.2019

CE DECLARATION OF CONFORMITY

ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski, ul. Zawisłańska 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

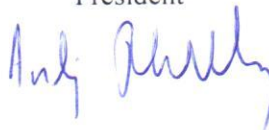
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

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



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

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.

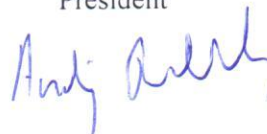
The assessment of conformity procedure has been held according to Annex VII of MDD Directive 93/42/EEC, and according to Annex VII of Medical Devices Essential Requirements Regulation from 12 January 2011 (Dz. U. nr 16 poz. 74), including modifications of the above regulation, implementing MDD Directive 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



„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

Warszawa, 25.04.2019

CE DECLARATION OF CONFORMITY

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

Anti-bedsore pneumatic cushion AT52107

Anti- bedsore mattress AT03102

Electric bed AT52201

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



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

Warszawa, 2014-05-06

CE DECLARATION OF CONFORMITY

ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski, ul. Zawisłańska 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
Irene Groniecka-Tarnkowska
Andrzej Tarnkowski
03-068 Warszawa, ul. Zawisłańska 43
tel.: 0 22 518 36 00 fax: 0 22 518 36 30
NIP: 524-21-23-915 0 22 518 36 31

Warszawa, 2016-01-04

CE DECLARATION OF CONFORMITY

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

WALKERS: AT02001; AT02002; AT02003; AT02004; AT02005; AT02006; AT02007;

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 ISO 13485:2003, EN ISO 9001:2008

Andrzej Tarnkowski
President



„ANTAR” Sp. Jawna
Irene Groniecka-Tarnkowska
Andrzej Tarnkowski
03-068 Warszawa, ul. Zawisłańska 43
tel.: 0 22 518 36 00 Fax: 0 22 518 36 30
NIP: 524-21-23-915 0 22 518 36 31

Warszawa, 22.06.2015

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:

Hedgehog type sitting cushion AT03008

Elliptical sittinh cushion AT03009

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



„ANTAR” Sp. Jawna
Irene 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

Warszawa, 11.09.2017

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

**Arm and shoulder orthosis the type „Dessault”: AT04001; AT04002; AT04004
Mesh arm sling AT04003**

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

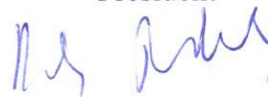
The assessment of conformity procedure has been held according to Annex VII of MDD Directive 93/42/EEC, and according to Annex VII of Medical Devices Essential Requirements Regulation from 12 January (Dz. U. nr 16 poz. 74), including modifications of the above regulation, implementing MDD Directive at 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 (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 ISO 13485:2003, EN ISO 9001:2008

„ANTAR” Sp. Jawna
Irene 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

Andrzej Tarnkowski
President



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:

Spinal orthosis TLSO ULTRA BREATH AT04501

Spinal orthosis LSO ULTRA BREATH AT04502

Lumbo- Sacral Belt AT04503

Lumbo- sacral support "industrial") AT04504

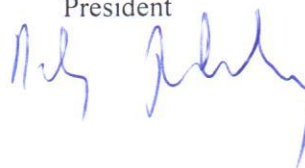
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

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



„ANTAR” Sp. Jawna
Irene 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

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:

Abdominal belt AT04601, AT04602

Abdominal belt for patients with stoma AT04603

Abdominal belt with brace AT04604

Abdominal belt ULTRA BREATH AT04605

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



„ANTAR” Sp. jawna
Irene 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

Warszawa, 25.04.2019

CE DECLARATION OF CONFORMITY

ANTAR Sp. J. I. Groniecka-Tarnkowska, A. Tarnkowski, ul. Zawisłańska 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

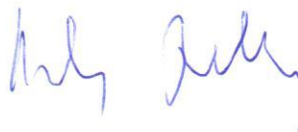
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule I.

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



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

Warszawa, 2013-03-19

CE DECLARATION OF CONFORMITY

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

Anti Decubitus Mattress with pump: AT52101; AT52102

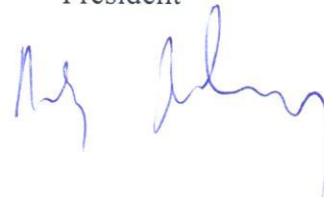
have been classified as medical devices, Class I, without measuring functions, non-sterile, according to Rule XII.

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 60601-1-2, EN ISO 60601-1, EN ISO 13485:2003; EN ISO 9001:2008.

Andrzej Tarnkowski
President



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