

Declaration of conformity for Medical Devices

Vicair BV
Koetserstraat 10
1531 NX Wormer
THE NETHERLANDS

We hereby declare that the Class I products specified below meet the relevant provisions of the European Medical Device Directive 93/42/EEC. The conformity assessment procedure followed is set out in Annex VII (Declaration of Conformity) of the Medical Device Directive. This Declaration of Conformity covers the CE marked products specified on the attached product list.

General applicable directives:

- Besluit medische hulpmiddelen van 30 maart 1995 in het Staatsblad 243
- Medical Device Directives: Council Directive 93/42/EEC concerning medical devices (MDD 93/42/EEC).
- Directive Packaging and waste: 94/62/EG.

Standards: (latest version)

- Harmonised Standards (published in the Official Journal of the European Communities) applicable to these products are:
EN-ISO 9001:2008 and EN-ISO 13485:2003 (quality management system);
EN 12182:2012 and subsequent product standards;
Risk Analysis carried out according to EN 14971:2012;
Guidelines Vigilance System MEDDEV 2.12/1;
Guidelines to the Classification MEDDEV 10/93.

Details of the products are laid down in the Technical File, which is present at the above mentioned address.

The Technical File complies with the requirements of the Directive MDD 93/42/EEC.



Date: 01-11-2015

M. Rogmans
General Manager



Date: 01-11-2015

R.N. Winkel
QA Manager



Product List

*Annex to Declaration of Conformity
For products of the category: Class I*

Standard models:

<u>Name of the product</u>	<u>Available variants (sizes in cm)</u>
Liberty PT*	40x40/40x45/43x43/45x40/45x45
Pelvic Stabilizer	40x45/40, 43x43, 45x45/40
Liberty Back System	3 Sizes
Liberty TC	2 Sizes
Liberty Ocean	1 Size
Academy Twin 6/10*	40x40/40x45/43x43/45x40/45x45
Academy Positioner Plus 6/10*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Adjuster 6/10 (12)*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Vector 6/10*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Vector O2 6/10	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Active 6/9	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Back System	8 Sizes
Academy Flex Back	41x55/45x55/49x55
Academy nXt Back	16x16/18x16/20x16/16x20/18x20/20x20"
Academy Matrix Elite Air	40x40/40x45/40x50/43x40/43x45/43x50/45x40x45x45/45x50/48x40/ 48x45/48x50/50x40/50x45/50x50
Anatomic Back	35x32/40x32/40x40/40x48/45x40/45x48/45x56/50x48/50x56
Vicair Strap Back	Width:30/35-40/45-50/43, Height: 32/40/48/56.
Academy Multi Functional Back	36x45/36x58/37x54/40x54/41x45/41x58/45x54/46x45/46x58/50x54/50x58
Academy Multi Functional Head	27x14
Academy Multi Functional Seat*	37x52/40x52/45x52/50x52
Academy Butterfly	40x20/45x20/50x20
Academy Allrounder	1 Size
Academy Junior Back System	25/30/35
Academy Junior Vector*	25x25/30x30/35x35
Academy Replacement Mattress	ARM3: 80x200/90x200/60x120 ARM415 (Dynamica): 80x200/90x200/100x200/70x140 ARMVS(3/415) : 80x20/90x20



Academy Centre Relief*	43x43/45x45
Academy Pommel Cushion & Pommel*	40x40/40x45/43x43/45x40/45x45/45x50 ; pommel: 10x13/10x14/10x15/10x17
Academy Asymmetric Cushion*	left and right
Academy Xxtra*	55x45/55x50/55x55/55x60/55x65/60x45/60x50/60x55/60x60/60x65/ 65x45/65x50/65x55/65x60/65x65

*Includes both Comfair and Incontinence covers

Custom made sizes can be made, but are subject to prior approval of the General Manager.

Special models:

Name of the product

Available variants (sizes in cm)

Liberty ST	40x40/43x43/45x45
Academy Junior Adjuster 4/6 & Pommel	cushion 4: 25x25/28x28/30x30 ; cushion 6: 33x33/35x35 ; pommel: 14/16
Academy Sling	110
Academy Bariatric	55x45/55x50/55x55/60x50/60x55/60x60/60x65
Academy Positioner Kuschall	35x40/40x40/40x43/40x45/43x40/43x43/45x40/45x45
Academy Pos Easy Seat for Doove	37x46/37x53/42x46/42x53/47x46/47x53
Academy Invacare Adjuster	37x52/40x52/45x52/50x52
Academy Vicair Inside Invacare	45x52
Academy Vicair Inside Invacare Back	41x45
Academy Vicair Inside Handicare Seat	37x52/44x52
Academy Vicair Inside Handicare Back	37x51/50x55
Academy Vicair Inside Handicare Head	27x14
Academy Vicair Inside Meyra	46x45
Academy Ergoshop Positioner	47x47/50x50
Academy MaxPro 8/10 (deep)	35x40/35x45/40x40/40x45/40x50/43x43/45x40/45x45/45x50
Academy Plankzitting	41x52/46x52/51x52
Etac Inlay	39x30x7
Reverse cover (Canada)	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Heel Protector	ST / XL

Change(s):

- Rev. 01: update of product list, Liberty Back System
- Rev. 02: update of product list, ARM415 (Dynamica)
- Rev. 03: update of standards and product list, ARMVS & client specific products
- Rev. 04: update of product list, LTC & Vector
- Rev. 05: update of product list, ARM415
- Rev. 06: update of product list, Academy Junior Vector
- Rev. 07: change of address
- Rev. 08: update of product list, Academy Vector 6
- Rev. 09: update of product list, ACR, XXtra, AAD12, APZ and new layout.
- Rev. 10: update of product list, Etac inlay, Heel Protector
- Rev. 11: update of product list, Academy Active
- Rev. 12: update of product list, Change in sizes of the Academy Active
- Rev. 13: update of product list, Change in sizes of the Academy Active, LTC3, Anatomic back
- Rev. 14: year added to standard listing
- Rev. 15: update of product list, Change in sizes of the Academy Active, Academy Flex back, Academy nXt back, Reverse cover, Academy Matrix Elite Air
- Rev. 16: update of product list, Vector O2

