



# Declaration of conformity for Medical Devices

Vicair BV  
Bruynvisweg 5  
1531 AX Wormer  
THE NETHERLANDS

**W**e 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 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.

A handwritten signature in black ink, appearing to read "M. Rogmans".

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Date: 04-04-2018

M. Rogmans  
General Manager

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Date: 04-04-2018

L. Wagemans  
QA Manager



# Product List

## Annex to Declaration of Conformity

### For products of the category: Class I

#### Standard models:

##### Liberty cushions

Vicair Liberty	Vicair Liberty Ocean
Vicair Liberty Profile	Vicair Liberty Back Cushion
Vicair Liberty TC	Pelvic Stabilizer

##### Academy cushions

Vicair Academy Twin	Vicair Academy Centre Relief
Vicair Academy Positioner	Vicair Academy Pommel cushion
Vicair Academy Adjuster	Vicair Academy Asymmetric cushion
Vicair Academy Vector	Vicair Academy Xtra (Bariatric)
Vicair Academy Junior Vector	Vicair Academy Allrounder
Vicair Academy Active	Vicair Academy Multifunctional Seat

##### O2 cushions

Vicair Academy Vector O2  
Vicair Academy Adjuster O2  
Vicair Academy Active O2  
Vicair Academy Allrounder O2

##### Academy back cushions

Vicair Academy Multifunctional Back	Vicair Academy Multifunctional Head
Vicair Academy Junior Back System	Vicair Armadillo back
Vicair Academy Back System	Vicair Academy Anatomic Back
Vicair Academy Flex Back	Vicair Academy MatrX Elite Air
Vicair Strap Back	

##### Academy Mattresses

Academy Replacement Mattress  
Academy Replacement Mattress Inlay

\* Includes Comfair, Incontinence and top covers, air exchange cover, reversible cover.

\* All Vicair Academy cushions are available in all standard sizes.

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



### Special or non-current models:

Liberty ST  
Liberty Basic

Liberty PT (PPS)

Academy Junior Adjuster 4/6 & Pommel  
Academy Sling  
Academy Bariatric  
Academy Positioner Kuschall  
Academy Pos Easy Seat for Doove  
Academy Vicair Inside Handicare Head  
Academy MaxPro 8/10 (deep)  
Academy Plankzitting

Academy Vicair Inside Invacare  
Academy Vicair Inside Invacare Back  
Academy Vicair Inside Handicare Seat  
Academy Vicair Inside Handicare Back  
Academy Invacare Adjuster  
Academy Vicair Inside Meyra  
Academy Ergoshop Positioner  
Etac Inlay

Reverse cover (Canada)  
Heel Protector

### 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
- Rev. 17: update of product list, new address, new layout.
- Rev. 18: update of product list, ARM inlay, Armadillo back, Liberty Basic & standard ISO9001 expired.
- Rev. 19: update of product list, Vicair Liberty, Vicair Liberty Profile
- Rev. 20: update of product list, top cover
- Rev. 21: update of product list, Vicair Academy Adjuster O2, Vicair Academy Active O2, Vicair Academy Allrounder O2,