



Declaration of Conformity for Medical Devices

Vicair BV
Bruynvisweg 5
1531 AX 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 13485:2016 (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".

Date: 03-10-2019

M. Rogmans
CEO

A handwritten signature in black ink, appearing to read "L. Wagemans".

Date: 03-10-2019

L. Wagemans
Quality 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	

Vicair cushions

Vicair Twin	Vicair Centre Relief
Vicair Positioner	Vicair Pommel cushion
Vicair Adjuster	Vicair XXtra (Bariatric)
Vicair Vector	Vicair AllRounder
Vicair Junior Vector	Vicair Multifunctional Seat
Vicair Active	

Vicair O2 cushions

Vicair Vector O2	Vicair Pommel cushion O2
Vicair Adjuster O2	Vicair Twin O2
Vicair Active O2	Vicair Centre Relief O2
Vicair AllRounder O2	Vicair Junior Vector O2
Vicair XXtra O2	Vicair Multifunctional O2

Vicair back cushions

Vicair Multifunctional Back	Vicair nXt Armadillo Back
Vicair Anatomic Back	Vicair Flex Back
Vicair Matrix Elite Air	Vicair nXt VC Back
Vicair Butterfly	Vicair Strap Back

Vicair Mattresses

Vicair Replacement Mattress
Vicair Replacement Mattress Inlay

* Includes Comfair, Incontinence and Top Covers, Air Exchange Covers, Reversible Covers.

* All Vicair 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
Pelvic Stabilizer
Academy Back System

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
Academy Multifunctional Head
Academy Junior Back System

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,
- Rev. 22: update of product list, Vicair XXtra O2
- Rev. 23: update of product list, Vicair Academy Asymmetric cushion added to non-current models
- Rev. 24: update of product list, Vicair Academy Pommel O2, Vicair Academy Twin O2
- Rev. 25: update of product list, Pelvic Stabilizer added to non-current models, ISO 13485 year update
- Rev. 26: update of product list, added: Vicair Centre Relief O2, Junior Vector O2, Multifunctional O2. Name-change: Academy removed from all cushions.