



Declaration of Conformity for Medical Devices

Vicair BV
Bruynvisweg 5
1531 AX Wormer
THE NETHERLANDS

This declaration of conformity is issued under the sole responsibility of Vicair. We hereby declare that the Class 1 medical devices specified in the attached product list meet the provision of the Medical Device Regulation (EU) MDR 2017/745. This declaration is supported by the Quality System approval to ISO 13485 issued by DEKRA Certification B.V.

All supporting documentation is retained at the premises of the manufacturer.

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 Medical Device Regulation (EU) MDR 2017/745.

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

Date: 02-03-2022
Wormer

M. Rogmans
CEO

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

Date: 02-03-2022
Wormer

L. Wagemans
Quality Manager



Product List

Annex to Declaration of Conformity

For products of the category: Class I according to MDR2017/745, Annex VIII

Standard models with Basic-UDI:

Vicair O2 cushions – 8717261VIC001VK

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 4	Vicair Hygiene

Vicair cushions – 8717261VIC001VK

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 back cushions – 8717261VIC001VK

Vicair Multifunctional Back	Vicair Multifunctional O2 Back
Vicair Anatomic Back	Vicair Flex Back
Vicair nXt VC Back	Vicair Strap Back
Vicair Butterfly	Vicair nXt Armadillo Back
Vicair Back Connector	

Liberty cushions – 8717261VIC002VM

Vicair Liberty	Vicair Liberty Ocean
Vicair Liberty Profile	Vicair Liberty Back Cushion
Vicair Liberty TC	

Vicair Mattresses – 8717261VIC003VP

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.

Intended uses:

The Vicair Cushions are intended to equally distribute body pressure and to help position wheelchair users.

The Vicair Allrounder is intended to equally distribute body pressure and offer protection for wheelchair users out of the wheelchair.

The Vicair Liberty Cushions are intended to equally distribute body pressure for wheelchair users.

The Vicair Mattresses are intended to equally distribute body pressure and to help position bed rested patients.



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
Vicair MatrX Elite Air

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: Vicair 4 added to Vicair O2 cushions
- Rev. 02: Basic-UDI added
- Rev. 03: Vicair Hygiene added to Vicair O2 cushions
- Rev. 04: Vicair Back Connector added to Vicair back cushions