



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: 02-12-2020
Wormer

M. Rogmans
CEO

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

Date: 02-12-2020
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:

Vicair O2 cushions

Vicair Vector O2
Vicair Adjuster O2
Vicair Active O2
Vicair AllRounder O2
Vicair XXtra O2
Vicair 4

Vicair Pommel cushion O2
Vicair Twin O2
Vicair Centre Relief O2
Vicair Junior Vector O2
Vicair Multifunctional O2

Vicair cushions

Vicair Twin
Vicair Positioner
Vicair Adjuster
Vicair Vector
Vicair Junior Vector
Vicair Active

Vicair Centre Relief
Vicair Pommel cushion
Vicair XXtra (Bariatric)
Vicair AllRounder
Vicair Multifunctional Seat

Vicair back cushions

Vicair Multifunctional Back
Vicair Anatomic Back
Vicair nXt VC Back
Vicair Butterfly

Vicair Multifunctional O2 Back
Vicair Flex Back
Vicair Strap Back
Vicair nXt Armadillo Back

Liberty cushions

Vicair Liberty
Vicair Liberty Profile
Vicair Liberty TC

Vicair Liberty Ocean
Vicair Liberty Back Cushion

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.

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