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 13485:2003 (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: 16-03-2018

R. Winkel
General Manager

Date: 16-03-2018

L. Wagemans
QA Manager

Product List

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

Vicair O2 models:

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

* Includes Comfair, Incontinence and top covers.

* All Vicair cushions are available in all standard sizes.
  Custom made sizes can be made, but are subject to prior approval of the Quality Manager.