

## Declaration of Conformity for Medical Devices

**Vicair BV**  
**Koetserstraat 14**  
**1531 NX 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:

- Harmonised Standards (published in the Official Journal of the European Communities) applicable to this products are:  
EN-ISO 9001, EN 46001, EN 1441, Guidelines Vigilance System, MEDDEV 2.12/1, Guidelines to the Classification MEDDEV 10/93 MEDDEV 10/93 and relevant product Standards

Details of the products lay down in the Technical File, which is present at above-mentioned address. The Technical File and the Design Dossier comply with the requirements of the Directive MDD 93/42/EEC.

Approval Board:	Signature: 	Date: 24-01-2002
Approval QA/RA manager:	Signature: 	Date: 24-01-2002

Change(s):



Vicair BV, Koetserstraat 14, 1531 NX Wormer, The Netherlands  
Tel. +31 (0)75 640 1191, Fax +31 (0)75 640 1274  
E-mail: info@vicair.com, Website: www.vicair.com

## Product List

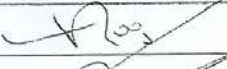
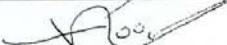
Annex to Declaration of Conformity 1601-01

Vicair BV  
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For products of the category: Class I

Name of the product  
Academy Cushions  
Academy Back Supports  
Academy Mattresses  
Liberty Cushions

Available variants  
different sizes  
different sizes  
different sizes  
different sizes

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