

Declaration of Conformity for Medical Devices

Vicair BV
Koetserstraat 14
1531 NX 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:

- Harmonised Standards (published in the Official Journal of the European Communities) applicable to these products are:
NEN-EN-ISO 9001, NEN-EN-ISO 13485, EN 1441, Guidelines Vigilance System, MEDDEV 2.12/1, Guidelines to the Classification MEDDEV 10/93 and relevant product standards

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.

Approval General Manager: M. Rogmans	Signature: 	Date: 22/01/04
Approval QA/RA Manager: F. Koekkoek	Signature: 	Date: 22-01-04

Change(s): rev 01: update of product list

Product List

Annex to Declaration of Conformity 1601-01

Vicalr BV
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THE NETHERLANDS

For products of the category: Class I

<u>Name of the product</u>	<u>Available variants (sizes in cm)</u>
Liberty ST*	40x40/43x43/45x45
Liberty PT*	40x40/40x45/43x43/45x40/45x45
Pelvic Stabilizer	40x40/43x43/45x45
Liberty Back System	3 Sizes
Academy Twin 6*	40x40/40x45/43x43/45x40/45x45
Academy Twin 10*	40x40/40x45/43x43/45x40/45x45
Academy Positioner Plus 6*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Positioner Plus 10*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Adjuster 6*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Adjuster 10*	35x40/40x40/40x45/40x50/43x43/45x40/45x45/45x50/50x45/50x50
Academy Back System	8 Sizes
Academy Lateral	1 Size
Academy Thoracic	1 Size
Academy Multi Functional Back	36x45/41x45/46x45/37x54/40x54/45x54/50x54
Academy Multi Functional Head	27x14
Academy Multi Functional Seat*	37x52/40x52/45x52/50x52
Academy Butterfly	40x20/45x20/50x20
Academy Allrounder	1 Size
Academy Junior Adjuster 4*	25x25/28x28/30x30
Academy Junior Adjuster 6*	33x33/35x35
Academy Junior Pommel*	14/16
Academy Junior Back System	25/30/35
Academy Mattress	80x200/90x200/60x120

*Includes both Comfair and Incontinence covers

Custom made sizes can be made, but are subject to prior approval of the General Manager.

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Approval QA/RA Manager: F. Koekkoek	Signature: 	Date: 22-01-04

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