EC- DECLARATION OF CONFORMITY

Following the EC Directive concerning medical devices 93/42/EEC, annex VII.

I, the undersigned, agent of the following manufacturer:

Haelvoet nv
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8770 Ingelmunster  Fax: +32 (0) 51 48 73 19
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Declare hereby that the following product:

Olympia Bariatric
No.: 10550
Medical device class I (non-invasive device)

when installed, maintained and used in accordance with the manual, the rules of good craftsmanship, and the intended purpose complies with all necessary safety requirements and other relevant provisions of annex I of:

Medical Devices directive 93/42/EEC

The following norms have been applied to indicate the conformity:

EN 60601-1  Medical electrical equipment. Part 1: General requirements for basic safety and essential performance.
EN ISO 14971  Application of risk management to medical devices.

The above-mentioned product has been designed, produced and checked in accordance with the quality management system of ISO 9001:2008.

Ingelmunster, 02/03/2012

Signature:

Haelvoet Vincent
Managing director