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
Leon Bekaertstraat 8 **Tel.:** **+32 (0) 51 48 66 95**
8770 Ingelmunster **Fax:** **+32 (0) 51 48 73 19**
Belgium **Email:** **info@haelvoet.be**

Declare hereby that the following product:

Olympia Hospital XLow

No.: 11662

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 harmonised 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 60601-1-2 Medical electrical equipment. Part 1-2: General requirements for safety and essential performance – Secondary norm: Electromagnetic compatibility – Requirements and tests.

EN 60601-2-52 Medical electrical equipment. Part 2-52: Particular requirements for basic safety and essential performance of medical beds.

EN ISO 14971 Application of risk management to medical devices.

The conformity to the mentioned harmonised norms is certified by:

TÜV SÜD Product Service GmbH
Approval certificate Z1 15 02 84536 011

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

Ingelmunster, 08/07/2013

Signature:

Haelvoet Vincent
Managing director