

Lode B.V. Medical Technology

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0344

MANUFACTURERS DECLARATION OF CONFORMITY

Product identification

Productgroup:

Ergometers and Treadmills with and without built-in blood pressure

monitor and Stress Tables

Brand:

Lode

Type:

Corival (Nuclear/Pediatric/Recumbent), Excalibur Sport (PFM), Angio

and MRI-ergometers, Valiant (Plus/Rehab/Sport/OEM), Stress Tables (all

types)

Means of conformity

The product is in conformity with Medical Device Directive 93/42/EEC) and complies with all requirements of the EMC Directive (89/336/EEC and 92/31/EEC) based on test results using harmonized standards in accordance with article 10.1 of the EMC Directive.

Testing

Carried out by:

Lode B.V. Medical Technology

Zernikepark 16 9747 AN Groningen The Netherlands

Lode B.V. is ISO 9001:2000 and ISO 13485:2003 certified by KEMA

Standards used:

IEC 60601-1 / IEC 60601-1-2

IEC 60601-1-4:1996+A1:1999

NEN-ISO 9001:2000 ISO 13485:2003

Inspection and

Assessment reports:

KEMA-06.20333 1PCO

Manufacturer:

Lode B.V. Medical Technology

Zernikepark 16 9747 AN Groningen The Netherlands

Representative:

Function:

J.J.P. Wolters

Signature:

President & CEO

Date: February, 2009