

CERTIFICATE OF CONFORMITY
WITH EUROPEAN DIRECTIVE



Certificate No.: EU0502403
Order No.: 38690

We hereby certify that an examination has been carried out following the requirements of the national legislation "Regulation no. 25 of 12th January 1995 relating to medical devices pursuant to act no. 6 of 12th January 1995 relating to medical devices, transposing directive 93/42/EEC into Norwegian law to which the undersigned is subjected, confer EEA agreement, proposition no. 100 (1991-92) special appendix no. 2, volume 2A/3 A, goods, chapter XXX". We certify that the production quality system conforms to the relevant provisions of the Annex given below:

Name and address of the manufacturer: Waters Medical Systems, Inc.
2112 15th Street, N.W.
Rochester, MN 55901,
USA

Device category: Kidney Perfusion Monitors and Whole Blood Oxygen Measurement Medical Devices

Models: See Appendix 1 to this certificate

Risk class as defined by the manufacturer: IIa

Standards/provisions: The audit of the quality system was based upon and assessed according to the provisions in Annex II of the EC-Directive 93/42/EEC (with the exemption of section 4.)

Date of audit: 2004-10-27

Date of the end of the validity: 2010-03-01

Nemko EC notification No.: 0470

On this basis the manufacturer or the European authorised representative may draw up an EC / EEA Declaration of Conformity and affix the CE-marking as indicated below together with the Nemko EC notification number to each conforming product as long as the conformity audit and inspection procedure required by the EC directive will be fulfilled.

Date of issue: 2005-02-03

Date of verification: 2005-02-03

Signature: Frank Skarpsno
Lead auditor /Principal Engineer

Signature: Arild R. Hansgård
Principal Engineer

CE 0470

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Manufacturer: Waters Medical Systems, Inc.
Device category: Kidney Perfusion Monitors and Whole Blood Oxygen Measurement
Medical Devices

Appendix 1:

The certificate referred to above includes the following models:

RM3 Renal Preservation System

Oxicom 2100

Oxicom 3000

Date: 2005-02-03

Frank Skarpsno