SIEMENS

EC DECLARATION OF CONFORMITY

according to Annex II Directive 93/42/EEC of June 14, 1993

Manufacturer:

Siemens Medical Solutions Inc.

Division:

Nuclear Medicine Group

Address:

2501 North Barrington Road

Hoffman Estates, Illinois, 60195 USA

Authorized EU Representative:

Siemens AG, Medical Solutions Group

Henkestrasse 127 D-91052 Erlangen

Medical device:

Nuclear Medicine Gamma Camera

Product identification:

See next page

Classification:

Class IIa (According to Rule 10 of Annex IX to

Council Directive 93/42/EEC)

We declare the compliance of the above medical device with the requirements of the Council Directive 93/42/EEC of June 14, 1993. Any modification of the medical device not authorized by us will invalidate this declaration.

The conformity of the full quality assurance system is certified by:

BSI Product Services Maylands Avenue Hemel Hempstead

Hertfordshire HP2 4SQ UK

The identification number of the notified body for implementation of the procedure set out in Annex II to the above Directive is 0086.

Place and date:

Hoffman Estates, IL

January 14, 2005

Name:

Michael Reitermann

(Head of Division)

Ron Nolte

(Head of Regulatory Affairs)

ikm Nolte

Signature:

For conditions of guarantee and liability please refer to our General Conditions of Sale.

(Form 0313) Document No. 7761427 Rev06 Date 20050114 Refer to SOP0385

Product identification:

Product 1	E.cam 180 Fixed Dual Detector Gamma Camera	Part No. 5224741
Product 2	E.cam Single Detector Gamma Camera	Part No. 4381021
Product 3	E.cam Standard Single Detector Gamma Camera	Part No. 5961060
Product 4	E.cam Signature Series – Single Detector	Part No. 7333235
Product 5	E.cam Signature Series Standard Single Option	Part No. 7822948
Product 6	E.cam Signature Series 180-Fixed Option	Part No. 7822930

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(FRM0313-07) Document No. 761435 Rev.02 Date 20050114 Refer to SOP0385

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Product identification:

Product 1	E.cam Dual Detector Gamma Camera	Part No. 4381047
Product 2	E.cam Cardiac Imaging System	Part No. 5253385
Product 3	E.cam Duet Variable Angle Gamma Camera	Part No. 5984013
Product 4	E.cam Signature Series – Dual Detector	Part No. 7333250
Product 5	E.cam Signature Series – Duet Detector	Part No. 7333284