Carestream HEALTH

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility that the product(s) listed are made in accordance with Annex I, Essential Requirements, and ANNEX VII EC Declaration of Conformity [Directive 93/42/EEC], of the European Economic Community Medical Device Directive and the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002.

Manufacturer's Name and Address: Carestream Health, Inc.
150 Verona Street
Rochester, New York, USA 14608

Medical Device: Intensifying Screens and Cassettes for use with medical recording films

Product List:

Cassettes & Cassettes with Screens:

Kodak X-OMAT Cassettes
Kodak X-OMAT Cassettes with X-OMATIC Screens: Regular, UV/Blue 200
Kodak X-OMAT Cassettes with Lanex Screens: Regular, Medium, Fine, Fast, Medium Plus, Extraoral (Medium and Regular)
Kodak X-OMAT Cassettes with InSight Screens: HC Thoracic Imaging, VHC Thoracic Imaging, Pediatric, Pediatric Detail, Skeletal Regular, Skeletal Medium, Pediatric Ultra Detail
Kodak X-OMAT Cassettes with X-Sight Screens
Kodak X-OMAT Cassettes with Ektavision Screens: Extraoral
Kodak X-OMAT Cassettes with Leadless Screens
Kodak Trimatic Cassettes
Kodak Trimatic Cassettes with Lanex Screens: Regular, Medium, Fine, Fast
Kodak Trimatic Cassettes with X-Sight Screens
Kodak Trimatic Cassettes with Insight Screens: VHC Thoracic Imaging
Kodak Medical X-Ray Cassette with Kodak Green 400 Screen

Screens:

Kodak X-OMATIC Screens: Regular
Kodak Lanex Screens: Regular, Medium, Fine, Fast, Medium Plus, 150, 200, 250, 300, 400, Extraoral (Medium and Regular)
Kodak InSight Screens: HC Thoracic Imaging, VHC Thoracic Imaging, Pediatric, Skeletal Regular, Skeletal Medium, Pediatric Detail, Pediatric Ultra Detail
Kodak X-Sight Screens
Kodak Green Screens: 200, 400
Kodak Ektavision Screens: Extraoral
Kodak Portal Imaging Phosphor Plate

Cassettes and Screens for Mammography:

Kodak Min-R Cassettes
Kodak Min-R Cassettes with: Min-R, Min-R 2000 and Min-R 2190 Screens
Kodak Min-R 2 Cassettes with: Min-R, Min-R 2000, Min-R 2190, Min-R 2250, Min-R EV 150, Min-R EV 190, Min-R EV 250 Screens
Kodak Min-R Screens
Kodak Min-R EV 150, Min-R EV 190, Min-R EV 250 Screens
Kodak Min-R 2000 and Min-R 2190 Screens

Cassettes for Radiation Therapy & Oncology with Lanex screens:

Kodak X-OMAT Cassettes: L, V

Kodak Cassettes: EC-L Lightweight Regular, EC-L Lightweight Fast, EC-L Lightweight Slow, EC-V Lightweight Regular, EC-V Lightweight Fast
"End of List"

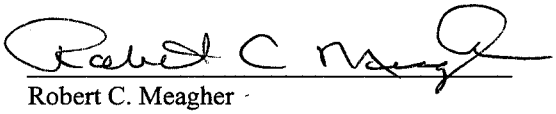
Device Classification:	Class I, Rule 1 (Council Directive 93/42 EEC, ANNEX IX) Class I, Rule 2.1 (Australian Therapeutic Goods (Medical Devices) Regulations 2002)
GMDN Code and Term:	35839 X-ray film cassette, automatic film changing 34317 X-ray intensifying screen
UMDNS Code:	14-474 X-ray film cassettes 14-486 Screens, X-ray film cassette
Scope of Application:	All declared products

Each kind of medical device to which the Declaration of Conformity (not requiring assessment by the Secretary) procedures have been applied complies with the applicable provisions of the essential principles and the classification rules before being supplied.

European Authorized Representative:
Carestream Health France
LES MERCURIALES
40, rue Jean Jaures
93176 BAGNOLET CEDEX
France

The reference product(s) and/or their components conform, at a minimum, to the following standard(s) and/or other equivalent normative document(s), pursuant to the provisions of the European Economic Community Medical Device Directive, and the Australian Therapeutic Goods (Medical Devices) Regulations:

EN ISO 13485: 2003	Medical devices - Quality management systems – Requirements for regulatory purposes
EN ISO 14971: 2007	Medical devices -Application of risk management to medical devices
EN ISO 4090:2004	Photography -Medical radiographic cassette/screens/films and hard-copy imaging films-Dimensions and specifications
EN 1041: 1998	Information supplied by the manufacturer with medical devices
EN 980: 2008	Symbols for use in the labelling of medical devices
ISO 7000:2004	Graphical symbols for use on equipment -Index and synopsis



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