



DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares that the product(s) listed are made in conformity with:
Medical Device Directive [Directive 93/42/EEC], ANNEX VII Conformity Assessment Procedure and the Australian
Therapeutic Goods (Medical Devices) Regulations 2002, Clause 6.6 of Schedule 3.

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

Medical Device: Non-X-ray Film, Sheet

Product List: DRYVIEW DVB Laser Imaging Film
DRYVIEW DVB+ Laser Imaging Film
DRYVIEW DVB+ Premium Laser Imaging Film
DRYVIEW DVC Laser Imaging Film
DRYVIEW DVE Laser Imaging Film
DRYVIEW DVM Mammography Laser Imaging Film
DRYVIEW DVM+ Mammography Laser Imaging Film
—End of List—

Device Classification: Europe - Class I, ANNEX IX , Rule I
Australia - Class I, Schedule 2, Part 2, Rule 2. 1

GMDN Code and Term: 40980. Medical x-ray film, non-screen

Scope of Application All declared products

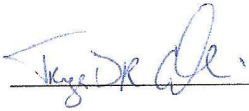
Each kind of medical device to which the Declaration of Conformity (not requiring assessment by the Secretary) procedures have been applied complies with the applicable provisions of the essential principles and the classification rules before being supplied.

Quality-Management-System Certified to EN ISO 13485 by:
BSI No. FM 701584
BSI No. FM 46141
TUV No. Q2N 17 11 61500 005
BSI No. FM 507315

European Authorized Representative: Carestream Health France
1, rue Galilée
93192 NOISY-LE-GRAND CEDEX
FRANCE

The relevant sections of the following European Union Harmonized standards apply to the listed product(s):

EN ISO 14971
EN 1041
EN ISO 15223-1
EN 62366



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