Carestream

DECLARATION OF CONFORMITY

Carestream Health, Inc., hereby declares under its sole responsibility 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:	TRIMAX TXB Laser Imaging Film TRIMAX TXM Laser Imaging Film TRIMAX TXM+ Laser Imaging Film TRIMAX TXE 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. Q6 061500 0007 BSI No. FM 507315
European Authorized Representative:	Carestream Health France SAS 207, Rue de Bercy 75012 Paris 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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