

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

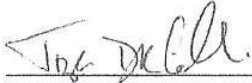
Issue date: 30 September 2020, (TRIMAX Laser Imaging Film)  
Revision K  
Carestream Health, Inc. | 150 Verona Street | Rochester, New York 14608 | USA

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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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