

**Certified Product:**

**Digital Radiography**

**X-ray system**

Model(s):

Clear Vision DR5000

Technical Data:

230 V ~, 50 / 60 Hz, 5.6 kVA



**Certificate Holder**

**Manufacturer**

JPI Healthcare Co., Ltd.

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608-ho,28, Digital-ro 33gil

265, Osongsaengmyeong 1-ro

Guro-gu, Seoul, 152-769

Osong-eup, Heungdeok-gu,

South Korea 18377

Cheongju-si, Chungcheongbuk-do,

28161, South Korea

The product is certified according to ISO/IEC Guide 67, *Conformity assessment — Fundamentals of product certification, System 3*, and in accordance with

**Standard for Medical electrical equipment - Part 1:  
General requirements for safety, UL 60601-1 1<sup>st</sup> Ed., Rev. April 26, 2006;  
CAN/CSA C22.2 No. 601.1-M90 (R2005 with updates No. 1 and 2),**

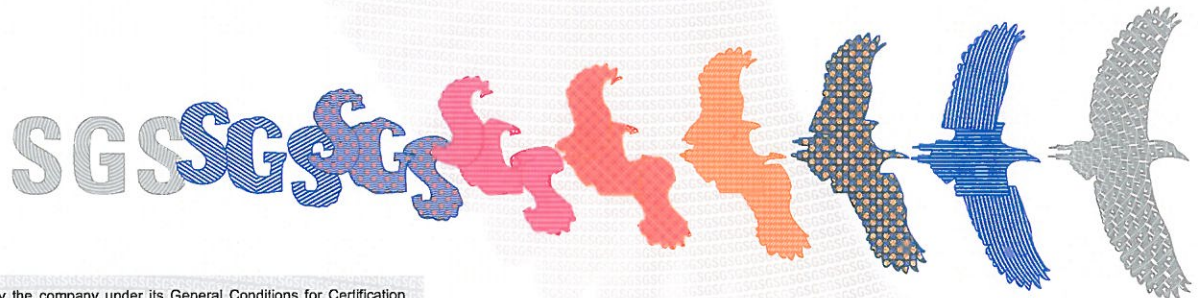
**Part 1-1: Collateral Standard: Safety Requirements for Medical Electrical  
Systems, IEC 60601-1-1 (second edition, issued 2000),**

**Part 1-3: Collateral Standard: General Requirements for Radiation  
Protection in Diagnostic X-Ray Equipment, IEC 60601-1-3  
(first edition, issued 1994),**

**Part 2: Particular requirements for the safety of high-voltage generators of  
diagnostic X-ray generator, IEC 60601-2-7 (second edition, issued 1998),**

**Part 2: Particular requirements for the safety of X-ray source assemblies  
and X-ray tube assemblies for medical diagnosis,  
IEC 60601-2-28 (first edition, issued 1993),**

**Part 2: Particular requirements for the safety of associated equipment of  
X-ray equipment, IEC 60601-2-32 (first edition, issued 1994)**



**Certificate: USTC/14/FAI/00188**

Contract Number: 710139

SGS Reference: 604837/01

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**X-ray system**  
Model(s): Clear Vision DR5000

This certificate is valid until 1 October 2018 unless the standard in question has been amended or superseded with significant changes in requirements, in which case, SGS has the right to shorten the validity of the certificate based on the legislation. This certificate includes the right to use the **SGS Product Certification Mark** under the condition that changes (if any) will be checked at SGS before the product is brought onto market and that the conditions for the **SGS USTC Certification Program** are met.

Authorized by

Effective date: 1 October 2015

Suwanee, GA

Paul Krauss

North American Certification Manager

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