Technical Document Summaries

Part J

Device:	Computer aided diagnostic software InferRead® DR Chest
Model:	InferRead DR Chest

Infervision Medical Technology Co., Ltd.

Revision History

Date of Amendment	Version No.	Revision Description	Revised by	Approved by
2022.9.30	A0	Product upgrade to V 1.0.1.1, the first version of the document	Liu Xianzhi	Chris Li
2023.3.16	A1	1. Revised the manufacture address. 2. Added the certificate reference number.	Liu Xianzhi	Chris Li
2023.6.25	A2	1. Revised the EMDN code. 2. Completed the certificate information.	Liu Xianzhi	Chris Li

EU Declaration of Conformity

Manufacturer: Infervision Medical Technology Co.,Ltd.

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SRN: DE-AR-000023562

Product: Computer aided diagnostic software InferRead® DR Chest

Brand name: InferRead® DR Chest

Intended use:

InferRead DR Chest is used for receiving chest radiograph DICOM image from medical imaging storage devices. It automatically analyzes the image and evaluates the probability of the chest abnormality (Tuberculosis). It shows the abnormal cases in a study list. It is used to assist the doctors for making diagnosis. It is not used for making diagnosis alone.

Basic UDI-DI: 697469271010P4

Device Nomenclature Code: Z11031192

Model List: InferRead DR Chest

Applied Standards List: See Annex 1

Classification: According to Annex VIII, Rule 11 of (EU) 2017/745 (MDR), the InferRead DR Chest is in class IIb.

Conformity Assessment Route: Annex IX, Regulation (EU) 2017/745 (MDR)

We hereby declare that the above-mentioned product meets the provisions of the Regulation (EU) 2017/745 (MDR) for medical devices. No medicinal product, including a medicinal product derived from human blood or human plasma, no tissues or cells of human origin or their derivatives, no CMR or endocrine-disrupting substances are incorporated into the device. All supporting documentation is retained under the premises of the manufacturer and Notified Body 2797, BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands.

CE 2797

Certificate	First Issue Date	Current Issue Date	Expiry Date
Certificate No.: MDR 777015	2023-06-21	2023-06-21	2028-6-20

The EU Declaration of Conformity is issued under the sole responsibility of the manufacturer:

The signature of the PRRC : 

Name **: Shaokang Wang**
Function (Company) **: Person Responsible for Regulatory Compliance**
Date **: 2023.6.25**
Location **: Beijing**

Annex 1

The standards/Common Specifications (CS) applicable for this product are listed as below:

Standard /Common Specifications (CS) No.	**Standard/Common Specifications (CS) Name**	**Date of Issue**	**Full/Partial Compliance**
EN ISO 14971:2021	Medical devices - Application of risk management to medical devices	2020-06-30	Full
ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971	2020-07-22	Technical guidance
IEC /TR 80002-1:2009	Medical device software Part 1: Guidance on application of ISO 14971 to medical device software	2009-9-23	Technical guidance
IEC/TR 80001-2-2:2012	Application of risk management for IT-networks incorporating medical devices -Part 2-2: Guidance for the disclosure and communication of medical device security needs, risk and controls.	2012-7-10	Technical guidance
ISO /TR 20416:2020	Medical devices - post-market surveillance for manufacturers	2020-7-1	Full
EN ISO 20417:2021	Medical device - Information supplied by the manufacturer	2021-04-30	Full
EN ISO 15223-1:2021	Symbols for use in the labelling of medical devices	2021-9-29	Full
EN ISO 13485:2016+A11:2021	Medical devices-Quality management systems-Requirements for regulatory purposes	2021-9-8	Full
EN 62366-1:2015/A1:2020	Medical devices - Application of usability engineering to medical devices	2020-8-19	Part applicable and compliance
IEC/TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	2016-04-27	Technical guidance
EN 62304:2006/A1:2015	Medical device software - Software life-cycle processes	2016-05-01	Part applicable and compliance
MDEG - 2008-12	Mandatory Languages Requirements for Medical Devices	2008-9-8	Part applicable and compliance
MDCG 2018-5	UDI assignment to medical device software	Oct-18	Full

Standard /Common Specifications (CS) No.	Standard/Common Specifications (CS) Name	Date of Issue	Full/Partial Compliance
MDCG 2019-7	Guidance on article 15 of the medical device regulation (MDR) and in vitro diagnostic device regulation (IVDR) on a 'person responsible for regulatory compliance' (PRRC)	Jun-19	Full
MDCG 2019-11	Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746	Oct-19	Full
MDCG 2019-16 rev.1	Guidance on cybersecurity for medical devices	Dec-19	Full
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software	Mar-20	Full
MDCG 2020-6	Guidance on sufficient clinical evidence for legacy devices	Apr-20	Full
MDCG 2020-7	Guidance on PMCF plan template	Apr-20	Full
MDCG 2020-8	Guidance on PMCF evaluation report template	Apr-20	Full
MDCG 2021-12	FAQ on the European Medical Device Nomenclature (EMDN)	Jun-21	Part applicable and compliance
MDCG 2021-24	Guidance on classification of medical devices	Oct-21	Part applicable and compliance
MDCG 2021-25	Application of MDR requirements to "legacy devices" and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC	Oct-21	Full
MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies	Jun-16	Full
MEDDEV 2.1/5	Medical Devices With a Measuring Function	1998-6-1	Part applicable and compliance
MEDDEV 2.12-2 rev. 2	Guidelines on post market clinical follow up	Jan-12	Full
MEDDEV 2.12/1 rev.8	Guidelines on a medical devices vigilance system	Jan-13	Full
/	Additional Guidance Regarding the Vigilance System as outlined in MEDDEV 2.12-1 rev. 8	Jul-19	Full

Standard /Common Specifications (CS) No.	Standard/Common Specifications (CS) Name	Date of Issue	Full/Partial Compliance
IMDRF/SaMD WG/N41FINAL:2017	Software as a Medical Device (SaMD): Clinical Evaluation	2017/9/21	Full
IMDRF MDCE WG/N55 FINAL:2019	Clinical evidence-key definitions and concepts	2019/10/10	Full
IMDRF MDCE WG/N56FINAL:2019	Clinical evaluation	2019/10/10	Full
IMDRF/GRRP WG/N47FINAL:2018	Essential principles of safety and performance of medical devices and IVD medical devices	2018/10/31	Full