EC Declaration of Conformity

Manufacturer: Infervision Medical Technology Co., Ltd.
Address: Room B401, The 4th Floor, Building 1 No.12, Shangdi Information Road, Haidian District, Beijing 100085, China.
Tel.: +86 (10) 86462323
Website: https://www.infervision.com

European representative: Infervision Europe GmbH
Address: Mainzer Str. 75, Wiesbaden 65189, Germany.
Tel: +49 (0)611 71185554

Product: Computer Aided Diagnostic Software

Model: InferRead DR Chest

Product Version: 1

GMDN Code: 63386

Applied Standards List: See Annex 1

Classification: According to Annex IX, Rule 10 of the MDD 93/42/EEC, InferRead DR Chest is in class IIa.

Conformity Assessment Route: Annex II, excluding section 4 of MDD 93/42/EEC

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC for medical devices. No human blood derivatives or tissues of animal origin are incorporated into the device. No medicinal substance is 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, Country: Netherlands

CE 2797

Certificate	Initially issued	Last renewal	Valid until
Full Quality Assurance System Certificate No.: CE 703557	**2020-02-24**	**2021-01-14**	**2024-05-26**

Signed for and on behalf of

Name : Zhenfeng Chen

Function (Company) : **Management Representative**

Date : Jan 15, 2021 **YYYY/MM/DD**

Location : **Beijing**