

Declaration of Conformity

Manufacturer Lucky Healthcare Co., Ltd.
Production address No.6 Lekai South Street, 071054 Baoding, Hebei, China
European Representative Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, Germany

Product Medical X-ray Film
Model Code KX121, KX123, KX171

Classification (MDD, Annex IX): II a

Conformity Assessment Route: MDD, Annex II.3

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer. we are exclusively responsible for this DOC.

DIRECTIVES

General applicable directives:

Medical Device Directive:
COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC).
Amended by DIRECTIVE 2007/47/EC of 5 September 2007

Notified Body: TÜV SÜD Product Service GmbH, Zertifizerstelle,
Ridlerstraße 65, 80339 München, Germany

Identification number: 0123

Certificate: No. G1 051867 0017 Rev.00

Expirate date of the Certificate: 2024-05-26

Date CE mark was affixed: 2005-07

Place, Date: Baoding 2020-09-24

Signature:

Zhu Zhiguang.

Name: Zhu Zhiguang
Position: General Manager