Declaration of Conformity

Manufacturer: Lucky Healthcare Co. ,Ltd.

Production address: No.6 Lekai South Street, Baoding,Hebei,China

European Representative: Shanghai International Holding Corp. GmbH (Europe) Eiffestraße 80, 20537 Hamburg, Germany

Product : Medical Dry Film

Model Code: KX410

Classification: I (MDR, Annex Ⅷ)

Conformity Assessment Route: DOC(Article 19) , CE TD(Annex Ⅱ+Ⅲ)

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

REGULATIONS

General applicable regulations:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Place, Date: Baoding 2023-04-28

Signature:

Name: Wen Jun

Position: General Manager

Digitally signed by Morozov Maria
Date: 2024.08.16 14:49:23 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ