EU Declaration of Conformity

MANUFACTURER AND ADDRESS:

NINGBO KONFOONG BIOINFORMATION TECH CO., LTD.

YESHAN ROAD, CHENGDONG NEW DISTRICT, ECONOMIC DEVELOPMENT ZONE, YUYAO, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA

SRN: CN-MF-000030466

AUTHORIZED European Representative: Share Info GmbH

Heerdter Lohweg 83, 40549 Düsseldorf

Product Name: Digital Slide Scanner

EMDN: W02069099

Type: KF-PRO-005, KF-PRO-020, KF-PRO-040, KF-PRO-120, KF-PRO-400

Basic UDI-DI: 0697533071113 8S9

Classification: Class A, rule 5

Conformity assessment route: issue the EU declaration of conformity referred to in Article 17, after drawing up the technical documentation set out in Annexes II and III

According to article 17 and Annex IV of the Regulation (EU) 2017/746 we draw up the <EU Declaration of conformity>. We herewith declare that the above-mentioned products meet the provisions of the Regulation (EU) 2017/746. All the supporting documentation is retained under the premises of the manufacture.

CE

General applicable regulation: REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on *in vitro* diagnostic medical devices.

Applicable standards:

EN ISO 14971：2019	EN ISO 18113-1：2011	EN ISO 18113-3：2011
EN 61326-1：2013	EN 61326-2-6：2013	EN 61010-1：2010
EN ISO 15233-1：2021	EN 62304：2006	EN 62366-1：2015

Statement about the manufacturer's exclusive responsibility.

Person keeping the technical documentation：

(Signature and title of authorized person): General Manager

(Place and date of issue of this document): YESHAN ROAD, CHENGDONG NEW DISTRICT, ECONOMIC DEVELOPMENT ZONE, YUYAO, ZHEJIANG PROVINCE, PEOPLE'S REPUBLIC OF CHINA 2022.07.03