

EU Declaration of Conformity

Manufacturer:

Name: NextVPU(Shanghai) Co., Ltd.

Address: 5th Floor, Building 7, No.3000 Longdong Road, Pudong New District, Shanghai, China.

SRN: CN-MF-000044578

European Representative:

Name: GRZAN GROUP SL

Address: C/ FUENCARRAL KM 29 MADRID 28004-MADRID

SRN: ES-AR-000039086

Product Name: AngelEye® Desktop Reader

Model: SR-D1

Basic UDI-DI: 697071352SR-D1GX

Intended Use: Covert printed documents into reading for the visually impaired people.

MDR Classification: Class I (rule 13)

Conformity Assessment Route:

following the Annex II + Annex III+ Article 19 of MDR (EU) 2017/745.

We, NextVPU(Shanghai) Co., Ltd. herewith under our sole responsibility declare that the above mentioned product meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Applied standards, common specification, guidance:

EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 15223-1:2021, MDCG 2021-24, MDCG 2019-15 rev.1, UN38.3, UL1642, IEC 62311:2020, IEC 62368-1:2020+A11:2020; ETSI EN 301 489-1 V2.2.3(2019-11), ETSI EN 301 489-17 V3.2.4(2020-09), EN 55032:2015+A11:2020; EN 55035:2017+A11:2020, EN61000-3-3:2013/A2:2021/AC:2022-01, EN IEC 61000-3-2:2019+A1:2021; ETSI EN 300328 V2.2.2(2019-07); ETSI EN 301 893 V2.1.1(2017-05)

Signature: *XIN PENG FENG*

Name: Xinpeng Feng

Place/Date: 15/10/2024

