# Declaration of Conformity

**For the following products:**

Infrared thermometer

(Product Name)

RAK-FI01, RAK-FI02, RAK-FI03, RAK-FI04, RAK-FI05

(Model Designation)

*is hereinafter confirmed to comply with the requirements set out in the Council Directive on the harmonization of the Laws of the Member States concerning Medical Device Directive (93/42/EEC As amended by 2007/47/EC)*

Applicable harmonized standards are:
EN ISO 13485: 2016, ISO 14971:2019, ISO/TR 14971: 2020, EN 60601-1: 2006+A1: 2013,
EN 60601-1-2: 2015, EN 60601-1-11: 2015, ISO 80601-2-56: 2017,
EN 60601-1-6: 2010+A1: 2015, EN 62366: 2008, EN 62304: 2006+A1: 2015,
ISO 15223-1: 2021, EN 1041: 2008
ISO10993- 1: 2018, EN ISO 10993-5: 2009, ISO 10993- 10: 2021, ISO 10993- 23: 2021,

**Conformity Assessment Route:**
Annex II excluding section 4 of Medical Device Directive

**Notified Body:**
DNV Product Assurance AS (NB No. 2460)
Veritasveien 3, 1363 Høvik, Norway

**The following European Authorized Representative is stated to the declaration:**
Company Name: MedPath GmbH

Company Address: Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

**The following manufacturer is exclusively responsible for making this declaration:**
Company Name: Shenzhen Ruiankang Technology Co., Ltd.

Company Address: Floor 1 and 2, No.8, Zhugushi Chunyang Industrial Park, Wulian Community, Longgang Street, Longgang District, Shenzhen

Song Jinzhi
(Legal Signature)

General Manager
(Position/title)

Shenzhen Ruiankang Technology Co., Ltd.
深圳市瑞安康科技有限公司
Authorized Signature

2023/11/06
(Date)