



Declaration of Conformity

MANUFACTURER: **BLZ Technology (Wuhan) Co., Ltd.**
C4166, Wuhan Overseas Scholar Business Park, No.11 Dongxin
Road, East Lake New Technology Development Zone,430074,
Wuhan, China

TRADEMARK: N.A.

SRN: Not available yet

EUROPEAN REPRESENTATIVE: **MedPath GmbH**
Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

SRN: DE-AR-000000087

PRODUCT: Intraoral Scanner

MODEL: INO100、INO100 Plus、INO200

BASIC UDI: 697124654IntraoralScan92

CLASSIFICATION: Class I (rule 13) according to Annex VIII of the Regulation(EU)
2017/745

CONFORMITY

ASSESSMENT ROUTE: Annex II + Annex III of MDR

INTENDED USE Intraoral Scanner is intended to obtain digital impression of teeth, gums, soft and hard tissues, to produce 3D scans for use in computer-assisted design and manufacturing of dental restorations.

CE CERTIFICATE NO.: N.A.

NAME AND ID OF THE NOTIFIED BODY: N.A.

WE HEREBY DECLARE UNDER OER SOLE RESPONSIBILITY THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE REGULATION(EU) 2017/745 ON MEDICAL DEVICES(MDR). ALL SUPPORTING DOCUMENTATTIONS ARE RETAINED UNDER THE PERMISES OF THE MANUFACTURER.

STANDARDS IEC 60601-1:2005+Corrigendum EN ISO 13485:2016

APPLIED: 1+Corrigendum 2+A1 EN ISO 14971:2012

IEC 60601-1-2:2014 EN 60601-1:2006+A11+A1+A12

EN 60601-1-2:2015

Signature: 
General Manager

Place and Date of Issue: WUHAN, CHINA, Jan 31, 2023