CE 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:	Vein Finder
MODEL:	VS30,VS400,VS500
BASIC UDI:	697124654VeinFinder55
GMDN:	48040-Infrared-light vein locator
CLASSIFICATION:	Class I (rule 13) according to Annex VIII of the Regulation(EU) 2017/745
CONFORMITY ASSESSMENT ROUTE:	Annex II + Annex III+ Annex IV of MDR
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 APPLIED:

IEC 60601-1:2005+Corrigendum 1+Corrigendum 2+A1

EN 60601-1:2006+A11+A1+A12

IEC 60601-1-2:2014

EN 60601-1-2:2015

EN ISO 13485:2016

EN ISO 14971:2019

BLZ TECHNOLOGY (WUHAN) CO., LTD. 201190178 76

Signature:

General Manager

Place and Date of Issue: WUHAN, CHINA, Aug 30, 2024

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