DECLARATION OF CONFORMITY TO COUNCIL REGULATION (EU)2017/745CONCERNING MEDICAL DEVICES

MANUFACTURER:	Shenzhen Creative Industry Co., Ltd. Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park, Songbai Road, Xili Street, Nanshan District, 518110 Shenzhen, PEOPLE’S REPUBLIC OF CHINA
SRN OF THE MANUFACTURE:	CN-MF-000009430
MEDICAL DEVICE:	Blood Pressure cuff
Model:	KM-232:15020010/15020029/15020063/15022001/15022402 /15020022 KM-233:15020011/15020060/15023001/15023001/15023402 KM-241:15020013/15020025/15020056/15024001/15024402 KM-242:15020014/15020057/15020059/15024002/15024403 KM-221: 15020030; KM-341:15020024; KM-342: 15020034 KM-343: 15020036
INTENDED USE:	The blood pressure cuffs are indicated for use in manual measurement and automatic non-invasive blood pressure monitoring .
CLASSIFICATION - ANNEX IX:	Class I, Rule 1
BASIC UDI-DI:	69419006Cuff35
CONFORMITY ASSESSMENT ROUTE:	Annex II+AnnexIII

WE, **Shenzhen Creative Industry Co., Ltd.**, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL REGULATION(EU) 2017/745 CONCERNING MEDICAL DEVICES; ALL SUPPORTING DOCUMENTATION ARE RETAINED UNDER THE PREMISES OF THE MANUFACTURER. WE ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

STANDARDS APPLIED:

ISO 15223-1: 2021	EN ISO 20417: 2021	ISO 10993-1: 2022
ISO 10993-5: 2009	ISO 10993-10: 2013	

EC REP

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraβe 80, 20537 Hamburg, Germany

SRN OF the EUROPEAN REPRESENTATIVE:DE-AR-000000001

PLACE, DATE OF DECLARATION: Shenzhen, Mar. 29, 2022

SIGNATURE:

NAME: ZHANG XIANG
POSITION: Management Representative