## DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC (INCLUDING DIRECTIVE 2007/47/EEC) CONCERNING 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

MEDICAL DEVICE: NIBP cuff

15024402/15023402/15024403/15020022/15020024/15022402/15

020030/15020029/15020056

CLASSIFICATION - ANNEX IX: Class I

CONFORMITY ASSESSMENT ROUTE: Annex VII

We, **Shenzhen Creative Industry Co., Ltd.**, Herewith declare that the stated medical devices meet the transposition into national law, the provisions of Council Directive 93/42/EEC of 14 June 1993 (Including Directive 2007/47/EEC) concerning medical devices; All supporting documentation is retained at the premises of the manufacturer.

STANDARDS A	APPLIED:
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ISO 13485: 2016	ISO 10993-5: 2009	ISO 10993-10: 2010
EN 1041: 2008+A1:2013	2011/65/EU	

EC REP

**EUROPEAN REPRESENTATIVE:** Shanghai International Holding Corp. GmbH (Europe)

Eiffestraβe 80, 20537 Hamburg, Germany

**START OF CE-MARKING:** 2014-12-09

PLACE, DATE OF DECLARATION: Floor 5, BLD 9, Baiwangxin High-Tech Industrial Park,

Songbai Road, Xili Street, Nanshan District, 518110

Shenzhen, PEOPLE'S REPUBLIC OF CHINA

SIGNATURE:

NAME: 56-311 FEB 05, 2020

**POSITION:** Management Representative