

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES**



MANUFACTURER:

CONTEC MEDICAL SYSTEMS CO., LTD

No.112 Qinhuang West Street, Economic & Technical
Development Zone, Qinhuangdao, Hebei Province,
PEOPLE'S REPUBLIC OF CHINA

MEDICAL DEVICE:

Blood Pressure Cuff IGN0055

CLASSIFICATION - ANNEX IX:

Class I , Rule 1

CONFORMITY ASSESSMENT ROUTE:

Annex VII

**LOT/BATCHES/SERIAL NUMBER, TYPE,
PERIODS OF MANUFACTURE :**

See Lable

WE, (CONTEC MEDICAL SYSTEMS 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 CONCERNING MEDICAL DEVICES;
INCLUDING, AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2007/47/EEC
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURE.

STANDARDS APPLIED: ANSI/AAMI EC53A:1998/(R)2008

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER:

CE 0123

(EC) CERTIFICATE(S):

G1 16 06 50972 050



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH(Europe)
Eiffestrasse 80, 20537 Hamburg Germany

START OF CE-MARKING:

2013-07-03 (Date or Lot or serial number)

PLACE, DATE OF DECLARATION:

QINHUANGDAO 2016.11.01

SIGNATURE:

President