

**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:**

ECG Cable And Accessories; BIT0370

**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:**

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President