

**Declaration of Conformity
To Council Directive 93/42/EEC of June 1993
Concerning Medical Devices**

DOCUMENT NO: RNK001

MANUFACTURER:



*RNK PRODUCTS, INC.
8247 DEVEREUX DRIVE, SUITE 101
VIERA, FL 32940 USA*

EUROPEAN REPRESENTATIVE:



*EMERGO EUROPE
PRINSESSEGRACHT 20
2514 AP, THE HAGUE
THE NETHERLANDS*

MEDICAL DEVICE:

*ELECTRONIC STETHOSCOPES SEE ATTACHED LIST
GMDNS 13754 ELECTRONIC STETHOSCOPE*

CLASSIFICATION - ANNEX IX:

CLASS IIA, RULE 10

CONFORMITY ASSESSMENT ROUTE:

ANNEX II w/o (4)

WE, THE MANUFACTURER, HEREWITH DECLARE THAT UNDER OUR SOLE RESPONSIBILITY 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 - AS AMENDED BY Directive 2007/47/EC.

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

NOTIFIED BODY:

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

IDENTIFICATION NUMBER

 0123

(EC) CERTIFICATE(S):

EC CERTIFICATE(S) NUMBER(S) G1 14 01 68373 008

START OF CE-MARKING:

DATE OF FIRST CE MARKING MARCH 21, 2009

PLACE, DATE OF DECLARATION:

VIERA, FL, USA, MAY 23, 2017

SIGNATURE:



*NAME: CHARLES R. ABBRUSCATO
POSITION: CEO*

**List of Models for RNK Electronic Stethoscopes and Accessories
under
Declaration of Conformity RNK001
August 20, 2013
Rev 4.0**

All of the electronic stethoscope models have the same intended use, MDD Class and Rule, GMDN Code and MBOG Code.

Intended Use:

The RNK Electronic Stethoscopes are intended for use to enable a clinician to listen to internal body sounds, such as heart and lung sounds, of a patient.

MDD Class and Rule:

Class IIa, Rule 10

GMDN Code:

GMDNS 13754 Electronic Stethoscope

NBOG Code:

MD 1302 Monitoring Devices of Physiological Devices

Models:

Device	CE Marking Start Date
TR-1 Module	March 21, 2009
TR-1/EF Module	March 21, 2009
TR-USB Module	March 21, 2009
CP-1 and CP-1/Ped Chest Piece	March 21, 2009
CP-2 and CP-2/Ped Chest Piece	March 21, 2009
PCP-1 Chest Piece	March 21, 2009
PCP-USB Chest Piece	August 20, 2013