

Declaration of conformity

Model : CRYOEACTION(COOLIPOTWIN)
Council Directive 93/42/EEC concerning Medical Device



1656-1, DONGHWARI, MUNMAKEUP, WONJUSI, GANGWONDO, KOREA

Declaration of Conformity

MANUFACTURER DAEYANG MEDICAL Co., Ltd.

1656-1, DONGHWARI, MUNMAKEUP,
WONJUSI, GANGWONDO, KOREA

EC AUTHORIZED REPRESENTATIVE

Name : DAEYANG UK LYD

Address : 145 THE HEART, WALTON-ON-THAMES,
SURREY, KT12 1GA

TEL :0044(0)1932 259 697

PRODUCT Group: LOW FREQUENCY THERAPY DIVICE

Model Name: CRYE ACTION(COOLIPOTWIN)

CLASSIFICATION Class :**IIa**

Applicated Rule: According to Annex (Including Section4) of the MDD 93/42/EEC

CONFORMITY ASSESSMENT ROUTE

Annex **II** of the MDD 93/42/EEC

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISION OF THE COUNCIL DIRECTIVE 93/42/EEC(AMENDED BY MDD 2007/47/EEC) FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED

EMC: EN 55011:2007+A2:2007, EN60601-1-2:2007

EN61000-3-2:2006(IEC61000-3-2), EN61000-3-3:1995+A1:2001+A2:2005,EN60601-1-2:2007

General requirements for safety : EN60601-1:1990+A1:1993+A2:1995+A13:1996

Particular requirements for the safety : EN60601-2-10:2000+A1:2001

NOTIFIED BODY SGS United Kingdom LTD

Address: 202B WorleParkway Weston-super-mare BS22 6WA

Identification Number: 0120

CERTIFICATE Number: EC(KR06/68090), QS(KR06/68091)

START OF CE-MARKING Date: 2006-04-18 Serial Number of First CE-Marking: DY24-00073



PLACE, DATE OF ISSUE

City: Seoul,

Korea Date : 2011-03-22

SIGNATURE

Name : **Min Jung Yun** Position : **President**

