Technology for Life
RADIAN QBIO

CE 1984

EC DECLARATION OF CONFORMITY

MANUFACTURER:	**RADIANQBIO Co., Ltd.** #1609~1611, HALLA-SIGMA VALLEY, 53, Gasan digital 2-ro, Geumcheon-gu, Seoul, Korea Tel. +82-2-852-1122, Fax. +82-2-6499-3076
EUROPEAN REPRESENTATIVE:	**S.B. PHARMA GMBH** Max-Planck Str., 39a D-50858, Koln, Germany Tel. +49 (0) 2234 988 1521, Fax. +49 (0) 2234 988 1521
COMMON/GENERIC NAME:	Automated External Defibrillator
TRADE/PROPRIETARY NAME:	Heart Guardian HR-501
CLASSIFICATION:	Class IIb by Rule 9 of Annex IX, Council Directive 93/42/EEC
CONFORMITY ASSESSMENT ROUT:	Annex II (excluding Section 4.), Full quality assurance system

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC AS AMENDED BY 2007/47/EC (MDD) FOR MEDICAL DEVICES AND DIRECTIVE 2011/65/EU (ROHS 2). ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED:	EN 1041:2008/A1:2013, EN ISO 10993-1:2009/AC:2010, EN ISO 13485:2012/AC:2012, EN ISO 14971:2012, ISO 15223-1:2012, EN 60601-1:2006/A1:2013, EN 60601-1-2:2007/AC:2010, EN 60601-1-6:2010, EN 60601-1-8:2007/AC:2010, EN 60601-1-11:2010, EN 60601-2-4:2011, EN 62304:2006/AC:2008, EN 62366:2008, MEDDEV 2.7.1 Rev.3
NOTIFIED BODY:	Notified Body Number 1984, Kiwa Belgelendirme Hizmetleri A.Ş. Tepeören Mevkii Ankara Asfaltı Maret Arkası ITOSB 9. Cadde No: 15 Tuzla, Istanbul, Turkey
(EC) CERTIFICATE(S):	M 4998.01 *(Issue date: 23 / November / 2017, Valid date: 22 / November / 2022)*
GMDN CODE:	47910
PLACE, DATE OF ISSUE:	In Seoul, 25 / January / 2019
SIGNATURE:	Mr. Beom-ki KIM / PRESIDENT

No. RD-DOC-111, Rev 5