



4309 Hacienda Dr, Suite 500
Pleasanton, CA 94588
USA

CE DECLARATION OF CONFORMITY

(NON TRANSFERABLE)

Authorized Rep.:

EC REP

MediTech Strategic Consultants B.V.
Maastrichterlaan 127
NL - 6291 EN Vaals
+31.43.306.3320

Models:

Remote Control Accessory

The above mentioned products
are in conformance with the
following Directives:

93/42/EEC (Medical Device Directive)
89/336/EEC (Electromagnetic Compatibility Directive)
73/23/EEC (Low Voltage Directive)
93/68/EEC (CE Marking Directive)
76/769/EEC (Dangerous Substances Directive)
2002/96/EC (WEEE Directive)

Device Classification:

Class I (93/42/EEC)

EMC Classification:

Class B, Group 1 (89/336/EEC)

Classification Rules Applied:

Rule12 (MEDDEV 2.4/1 Rev.9)

Conformity Assessment:

Annex VII

Date of Issuance:

January 12, 2011

Authorized Signature:

Andy Preston

Director of Engineering and Quality Assurance

Limits and Methods Verified:

None

Relevant Harmonized
Standards:

EN 980: 2008
EN 60601-1, 2nd Edition, + Amendment 1 & 2
EN 60601-1-2, 2nd Edition, + Amendment 1 & 2
EN 60601-1-4, 2nd Edition, + Amendment 1 & 2
EN ISO 14971: 2007