S- 6059645

–DECLARATION OF CONFORMITY–
TO
MEDICAL DEVICES DIRECTIVE 93/42/EEC

Manufacturer: Instromedix®
A Card Guard Company
6779 Mesa Ridge Road, Suite 200
San Diego, CA 92121-2909

Device: Cardiac Monitoring Equipment, King of Hearts Express AF
Device Models: LR080-XX
Device Options: N/A

We herewith declare that the above mentioned device(s) and accessories comply with the requirements of the EC Directive 93/42/EEC, that the conformity assessment procedures are completed, and the devices(s) is designed, manufactured, and tested in accordance with the information contained within the Technical File.

This declaration is based on:

MDD Classification and Rational: IIa per Annex IX, Rule 10
Conformity Assessment Procedure: MDD 93/42/EEC Annex II
Certification of Quality System: 19 January 2001
EC Certification Number: CE 57444
Issued by: British Standards Institution
Notified Body Number: 0086
Device Technical File
Completed By: Research and Development and Quality Engineering
Initial Release Date: May, 2002

Supplementary Information:

The product herewith has additionally been assessed and complies with the following specifications and standards:

Safety:
- EN 60601-1 (1990)
- EN 60601-2-25 (1993)
- EN60529

EMC:
- EN 60601-1-2 (1993) Group 1, Class B
- EN14971

Authorized EU Representative

Obelis s.a
34, Av.de Tervuren, bte 44
B-1040 Brussels, Belgium
Tel: (32) 2.732.59.54
Fax: (32) 2.732.60.03
E-Mail: mail@obelis.net

Issued by

Instromedix®
A Card Guard Company
San Diego, California U.S.A.

Engineering

Quality

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