

Revision	Change Description	DCO #	Date
A	Initial Release as a standalone document	E3402	9/10/08
B	Re-Release of 10-4601 and 10-4602 only	E3621	2/23/10
C	In error it was not recorded on Rev B the D of C was updated to include Directive 2007/47/EC showing Kirwan compliance to the Directive on March 21, 2010	E3668	3/21/10
D	Update format and with GMDN # & code	E3750	10/28/10
E	Add revision level to standards based on TUV's recommendations. Change wrong cert # and move expiry date	E3884	7/15/11
F	Add 10-4602J	E3871	11/16/11
G	Change Cert#. Scope of coverage now includes BP Coagulator.	E4043	5/24/12
H	Based on TUV audit: add "exclusively responsible," add ¶ 2, add TUV address. Update IEC 60601-1-1:2000 to IEC 60601-1:2005	E4207	5/14/13
I	TUV Auditor stated Irrigating cords are Class I under Rule 2, not Class II. Updating to put under Class I	E4238	6/6/13
J	Add 10-4601V	E4250	7/23/13
K	Remove 10-4601, 10-4602 (flying leads)	E4427	2/20/14
L	Update G2 cert expiration date & number	E4454	3/26/14
M	Add 10-4601J	E4545	9/18/14
N	Change notified body from TUV to SGS / CE # change from 0123 to 0120 as of 11/1/14	E4618	11/1/14
O	Correct date to 2020	E5242	1/17/17
P	Update date of expiration for EC Certificate	E5528	4/18/18
Q	Add GTIN numbers for each device. Add RoHS DoFC info. Revise 10993-1 to 2018 & add / update 60601-X to correct revisions.	E5734	7/31/19
R	Update the document for the new SGS CE number, new SGS NB, and the new cert number	E5795	12/16/19

**DECLARATION OF CONFORMITY
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL
DEVICES as amended by Directive 2007/47/EC**



MANUFACTURER:

Kirwan Surgical Products LLC
180 Enterprise Drive
Marshfield, MA 02050
USA

EUROPEAN REPRESENTATIVE:
(for Regulatory Issues only)



MPS, Medical Product Service GmbH
Borngasse 20
35619, Braunfels Germany
Tel. +49 (0)6442962073

PRODUCT:

Disposable Irrigation Bipolar Cord
(See Page 2 for Model Number)

CLASSIFICATION:

Class I, Sterile (Rule 2, Annex IX of the MDD)

UMDNS NUMBERS & CODES:

11496, "Cables/leads, Electrosurgical Units", and
14188, "Tubes, Connecting"

GMDN Number & Code:

47143, "Electrosurgical diathermy system cable, single use"

As manufacturer and exclusively responsible for this Declaration of Conformity, we herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of June 14, 1993 for medical devices as amended by Directive 2007/47/EC. This declaration applies to all CE Marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:

Biocompatibility	ISO	10993-1:2018
Electrical Safety	IEC	60601-1:2005
	IEC	60601-2-2:2017
	IEC	60601-1-2:2014

Notified Body:

SGS Belgium NV (CE 1639)
SGS House, Noorderlaan 87, 2030 Antwerp, Belgium

Identification Number:



Certificate:

EC Certificate No.: US19/819943477
(Annex V of the MDD)
Valid until May 24, 2024

START OF CE-MARKING :

February 8, 2010

Kirwan Surgical Products LLC	Declaration of Conformity: Disposable Irrigation Bipolar Cords
Page 2 of 4	Doc. No.: DC-113, Rev.: R

As manufacturer and exclusively responsible for this Declaration of Conformity, we herewith declare that the above-mentioned products meet the provisions of Directive 2011/65/EU of the European parliament and of the Council of June 8, 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. This declaration applies to all listed products manufactured from the date of issuance until it is either superseded by another declaration or withdrawn

All supporting documentation is retained under the premises of the manufacturer.

Start of RoHS Compliance: July 10, 2014

Place, Date of DofC Issue: Marshfield, Massachusetts, USA
Date: December 16, 2019

Signature: 
Scott Kirwan
President
Kirwan Surgical Products LLC

Kirwan Surgical Products LLC	Declaration of Conformity: Disposable Irrigation Bipolar Cords
Page 3 of 4	Doc. No.: DC-113, Rev.: R

DISPOSABLE IRRIGATION BIPOLAR CORDS

10-4601J	Disposable Irrigation Bipolar Cord, Gravity Drip, w/ 38mm Fixed Pins 00841019101834
10-4601V	Disposable Irrigation Bipolar Cord w/ 28.6mm Fixed Pins 00841019101841
10-4602J	Disposable Irrigation Bipolar M1000 Type w/38mm Fixed Pins 00841019101872