

Revision	Change Description	DCO #	Date
A	Initial Release	E3942	1/9/12
B	Line Extension, add 14-9000 and 14-9001 & Update Cert # which now includes BP Coagulators	E3996	5/22/12
C	Update G1 cert due to new expiration date (from 2013 to 2018), Based on TUV audit: add "exclusively responsible," add ¶ 2, Update IEC 60601-1-1:2000 to IEC 60601-1:2005	E4258	6/18/2013
D	Add new part numbers 14-9030, -9031, -9032, -9034	E4413	2/12/14
E	Change notified body from TUV to SGS / CE # change from 0123 to 0120 as of 11/1/14	E4618	11/1/2014

Kirwan Surgical Products LLC	Declaration of Conformity: Disposable Bipolar Suction Coagulator
Page: 1 of 3	Doc. No.: DC-116, Rev.: E

**DECLARATION OF CONFORMITY  
TO COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES**



**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 Bipolar Suction Coagulator  
(See Page 2 for Model Numbers)

**Classification:**

Class IIb (Rule 9, Annex IX of the MDD)

**UMDNS Number & Code:**

15579, "Electrodes, Electrosurgical"

**GMDN Number & Code:**

35703, "Electrosurgical diathermy system conducting unit,  
foot controlled 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 This declaration applies to all CE Marked devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.**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 and the notified body.**

**STANDARDS APPLIED:**

Electrical Safety	IEC	60601-1:2005
	IEC	60601-2-2:2009
EMC	IEC	60601-1-2:2007

**Notified Body:**

SGS  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK

**Identification Number:**

0120

**Certificates:**

EC Certificate No.: US14/841851  
(Annex II, Clause 3 and Paragraph 2 of the MDD)  
Expiration Date: June 8, 2018

**Start of CE-Marking:**

January 9, 2012

**Place, Date of Issue:**

Marshfield, Massachusetts, USA  
Date: November 1, 2014

**Signature:**

Scott Kirwan  
President  
Kirwan Surgical Products LLC

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Page: 2 of 3	Doc. No.: DC-116, Rev.: E

# DISPOSABLE BIPOLAR SUCTION COAGULATOR

14-9000	Disposable Bipolar Suction Coagulator 8Fr, 7.5 inch length
14-9001	Disposable Bipolar Suction Coagulator 11Fr, 7.5 inch length
14-9002	Disposable Bipolar Suction Coagulator 13Fr, 5.5 inch length
14-9004	Disposable Bipolar Suction Coagulator 15Fr, 5.5 inch length
14-9006	Disposable Bipolar Suction Coagulator 13Fr, 7.5 inch length
14-9008	Disposable Bipolar Suction Coagulator 15Fr, 7.5 inch length
14-9020	Disposable Bipolar Suction Coagulator 15Fr, 5.5 inch length, curved
14-9030	Disposable Bipolar Suction Coagulator 8Fr, 11 inch length
14-9031	Disposable Bipolar Suction Coagulator 11Fr, 11 inch length
14-9032	Disposable Bipolar Suction Coagulator 13Fr, 11 inch length
14-9034	Disposable Bipolar Suction Coagulator 15Fr, 11 inch length