

**Declaration of Conformity
T2004 01 A and T2004 02**

Manufacturer:

DePuy Mitek, Inc.
a Johnson & Johnson company
325 Paramount Drive
Raynham, MA 02767 USA

OEM:

Gyrus Medical, Fortran Road, St. Mellons
Cardiff CF3 0LT, United Kingdom

European Authorized Representative:

DePuy Ireland UC
Loughbeg, Ringaskiddy
Co. Cork, Ireland

Notified Body:

BSI
Say Building,
John M. Keynesplein 9,
1066 EP Amsterdam,
The Netherlands
Identification Number: 2797

Quality Management Certificate FM 704401
Quality Management Certificate MDSAP 685940
Full Quality Certificate CE 77316

Products: See attached list

Classification: Class IIb, Rule 9 of Annex IX of the MDD

We declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC of June 14, 1993 and amending directive 2007/47/EC concerning Medical Devices. All supporting documentation is retained under the premises of the manufacturer.

Conformity Assessment Route: Annex II.3 of the MDD

Start of CE Marking: See attached list

Julie Vafides
Associate Director, Regulatory Affairs

Date

Catalog Number	Description	CE Mark Date	GMDN Code	GMDN Description
225024	VAPR VUE RF Generator	July 6, 2010	11490	Electrosurgical system generator
225301	VAPR Side Effect Electrode 3.5mmX160mm	June 30, 1997	61872	Endoscopic electrosurgical electrode, bipolar, single use
225302	VAPR Angled Side Effect Electrode 3.5mmX160mm	June 30, 1997	61872	Endoscopic electrosurgical electrode, bipolar, single use
225303	VAPR End Effect Electrode 3.5mmX160mm	June 30, 1997	61872	Endoscopic electrosurgical electrode, bipolar, single use
225304	VAPR Angled End Effect Electrode 3.5mmX160mm	June 30, 1997	61872	Endoscopic electrosurgical electrode, bipolar, single use
225305	VAPR 90° Hook Electrode 3.5mmX160mm	June 30, 1997	61872	Endoscopic electrosurgical electrode, bipolar, single use
225312	VAPR Electrode Flex Side Effect 3.5mmX160mm	December 14, 1998	61872	Endoscopic electrosurgical electrode, bipolar, single use
225314	VAPR Flexible End Effect Electrode, 3.5mmX160mm	December 14, 1998	61872	Endoscopic electrosurgical electrode, bipolar, single use
225202	2.3 VAPR End Effect Electrode, 140mm	August 25, 1999	61872	Endoscopic electrosurgical electrode, bipolar, single use
225201	2.3 VAPR Side Effect Electrode, 140mm	October 26, 1999	61872	Endoscopic electrosurgical electrode, bipolar, single use
225211	VAPR 2.3 Side Effect Electrode (Short), 85mm	January 11, 2000	61872	Endoscopic electrosurgical electrode, bipolar, single use
225203	VAPR 2.3mm Wedge Electrode, 140mm	April 20, 2000	61872	Endoscopic electrosurgical electrode, bipolar, single use
225213	VAPR 2.3mm Wedge Electrode (Short), 85mm	April 20, 2000	61872	Endoscopic electrosurgical electrode, bipolar, single use
225252	VAPR Temperature Control End Effect Electrode, 2.3mmX140mm	August 31, 2000	61872	Endoscopic electrosurgical electrode, bipolar, single use
225360	VAPR LD Suction Electrode, 4.0mmX160mm	October 7, 2002	61872	Endoscopic electrosurgical electrode, bipolar, single use
225361	VAPR LP (Low Profile) Suction Electrode, 4.0mm X 160mm	December 5, 2003	61872	Endoscopic electrosurgical electrode, bipolar, single use
225370	VAPR S90 Electrode 4.0mm, 90° Suction w/Integrated handpiece	September 26, 2005	61872	Endoscopic electrosurgical electrode, bipolar, single use
227301	VAPR 3.5mm Side Effect Electrode with Integrated Handpiece	September 19, 2006	61872	Endoscopic electrosurgical electrode, bipolar, single use
227305	VAPR 3.5mm Hook Electrode with Integrated Handpiece	September 19, 2006	61872	Endoscopic electrosurgical electrode, bipolar, single use
227302	VAPR 3.5mm Angled Side Effect Electrode with Integrated Handpiece	April 20, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227203	VAPR 2.3mm Wedge Electrode with Integrated Handpiece	May 22, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227213	VAPR 2.3mm Wedge Electrode (Short) with Integrated Handpiece	May 22, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227355	VAPR S50 Electrode with Integrated Handpiece	June 19, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227312	VAPR Flexible Side Effect Electrode with Integrated Handpiece, 3.5mm X 160mm	July 2, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227211	VAPR 2.3 Side Effect Electrode (Short) with Integrated Handpiece, 85mm	July 20, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227202	VAPR 2.3 End Effect Electrode with Integrated Handpiece, 140mm	August 14, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use
227252	VAPR Temperature Control End Effect Electrode with Integrated Handpiece, 2.3mm x 140mm	October 15, 2007	61872	Endoscopic electrosurgical electrode, bipolar, single use

Catalog Number	Description	CE Mark Date	GMDN Code	GMDN Description
227504	VAPR Premiere50 Electrode with Integrated Handpiece	April 13, 2009	61872	Endoscopic electrosurgical electrode, bipolar, single use
227204	VAPR Premiere90 Electrode with Integrated Handpiece	August 5, 2009	61872	Endoscopic electrosurgical electrode, bipolar, single use
228147	VAPR CoolPulse 90 Electrode with Hand Controls	July 6, 2010	61872	Endoscopic electrosurgical electrode, bipolar, single use
228146	VAPR CoolPulse 90 Electrode with Integrated Handpiece	November 29, 2010	61872	Endoscopic electrosurgical electrode, bipolar, single use
228203	VAPR 2.3mm Wedge Electrode with Handcontrols	April 16, 2012	61872	Endoscopic electrosurgical electrode, bipolar, single use
228300	VAPR 3.5mm Side Effect Electrode with Hand controls	April 16, 2012	61872	Endoscopic electrosurgical electrode, bipolar, single use
228305	VAPR 3.5mm Hook Electrode with Hand controls	April 16, 2012	61872	Endoscopic electrosurgical electrode, bipolar, single use
228370	VAPR 4.0mm S90 Electrode with Hand controls	April 16, 2012	61872	Endoscopic electrosurgical electrode, bipolar, single use
228504	VAPR 3.0mm P50 Electrode with Hand controls	April 16, 2012	61872	Endoscopic electrosurgical electrode, bipolar, single use
225029	VAPR ARCTIC Suction Electrode, Dome Tip with Integrated Handpiece	August 25, 2014	61872	Endoscopic electrosurgical electrode, bipolar, single use
225030	VAPR ARCTIC Suction Electrode, Chisel Tip with Integrated Handpiece	September 8, 2015	61872	Endoscopic electrosurgical electrode, bipolar, single use
225028	VAPR TriPolar90 Suction Electrode	May 29, 2015	61872	Endoscopic electrosurgical electrode, bipolar, single use

End of List.