TÜV Rheinland
Product Safety GmbH

Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: SY 60006059 0001
Report No.: 21102077 002

Manufacturer: Future Medical Systems S.A.
265, Rte. de la Baronne

06640 St. Jeannet
France

Scope: Design, manufacturing, sales and servicing of surgical devices in endoscopy and arthroscopy

Replaces Certificate, Registration No.: SY 60005212 01

Cologne, 08.10.2003

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH

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TÜV Rheinland
Product Safety GmbH
Am Grauen Stein, D-51105 Köln

C E R T I F I C A T E

for a

Quality Management System

according to

EN ISO 9001:2000
EN ISO 13485:2000

TÜV Rheinland Product Safety GmbH hereby certifies that the

Manufacturer: Future Medical Systems S.A.
265, Rte. de la Baronne

06640 St. Jeannet
France

has established and maintains a quality management system. Conformance with the requirements of the standards has been audited.
The manufacturer is subject to a yearly surveillance audit.

Registration No.: SY 60006059 0001

Report No.: 21102077 002

Date of expiry: 07.10.2008

Scope: Attachment / Annexe

Certification Body

Cologne, 08.10.2003

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH TÜV Rheinland

fms GROUP

EC DECLARATION OF CONFORMITY

In accordance with the annex II.3 of the MDD directive 93/42/EEC

I, the undersigned, Mr. Patrick JANIN, Chairman and Managing Director of FUTURE MEDICAL SYSTEMS S.A., 265 route de la Baronne, F-06640 Saint-Jeannet, France, ensure and declare that the medical devices of Class **IIa** herewith enclosed, satisfy to the essential requirements of the annex I of the directive 93/42/EEC which applies to them.

FMS DUO®+ and accessories	
REF	***DESIGNATION***
4580	FMS DUO®+ (8000 RPM)
	Accessories:
4176	4 way pedal board
4172	2 way pedal board
8022	FMS Handpiece 8000 RPM : TORNADO
8050	Remote control

Saint Jeannet, The 6th February 2004

Patrick JANIN,
Chairman and Managing Director

+33 4 92 12 04 74 Tel - +33 4 92 12 04 75 Fax www.fmsgroup.com
FUTURE MEDICAL SYSTEMS S.A. 265, Route de la Baronne 06640 Saint-Jeannet France
N° TVA intracommunautaire : FR 53 383 617 988 - SA au capital de 614 400 Euros - RCS Grasse 383 617 988 - SIRET 383 617 988 00017 - APE 331 B

TÜV

Doc. 1/1, Rev. 1

TÜV Rheinland
Product Safety GmbH

Am Grauen Stein, D-51105 Köln

Attachment to
Registration No.: HD 60006057 0001
Report No.: 21102077 002

Manufacturer: Future Medical Systems S.A.
265, Rte. de la Baronne
06640 St. Jeannet
France

Scope: Products:

- ARTHROSCOPY PUMPS AND SHAVERS
- ARTHROSCOPY AND UROLOGY TUBINGS
- SHAVER BLADES
- UROLOGY FLUID MANAGEMENT SYSTEMS

Cologne, 30.06.2006

TÜV Rheinland Product Safety GmbH
TÜV Rheinland
Zertifizierungsstelle

Dipl.-Ing. I. Munkler

10/020 7.95Q

TÜV

APPROVAL

EC Directive 93/42/EEC Annex II, Article 3
Full Quality Assurance System
Medical Devices

Registration No.: HD 60006057 0001

Report No.: 21102077 002

Manufacturer: Future Medical Systems S.A.
265, Rte. de la Baronne

06640 St. Jeannet
France

Scope: Design, manufacturing, sales and servicing of surgical devices in endoscopy and arthroscopy

Products: see attachment

Date of Expiry: 07.10.2008

The Notified Body hereby authorizes the quality management system established and applied by the company mentioned above. The requirements of Annex II, Article 3 of the directive have been met. This approval is subject to periodic surveillance, defined by Annex II, Article 5 of the aforementioned EC Directive, and can be used by the company with the manufacturer's declaration of conformity.

Notified Body

Cologne, 08.10.2003

Dipl.-Ing. I. Munkler

TÜV Rheinland Product Safety GmbH
TÜV Rheinland
Zertifizierungsstelle

TÜV Rheinland Product Safety GmbH - Am Grauen Stein - D-51105 Köln
Accredited by Zentralstelle der Länder für Sicherheitstechnik (ZLS) and
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten (ZLG).

Notified under No. 0197 to the EC Commission.

CE The CE marking may be used if all relevant and effective EC Directives are complied with. CE