Medical Device Application

ARTG No : 169348

Class IIa
Status: Approved

Application Change history

Application Progress Date	
Date received:	11/02/2010

Review Information	
Review flag:	Restrictions on Scope of evidence
Auto review required:	No

Device Product Characteristics

Is the device, or any form of the device, supplied sterile: No
Is the device intended to be invasive: Yes
Is the device, or any form of the device, intended for single use: No
Is the device an active device: Yes
Does the device contain material or ingredients of microbial origin: No
Does the device contain material or ingredients of recombinant origin: No
Does the device contain material or ingredients manufactured or formulated using a genetically modified organism: No
Does the device contain material or ingredients of Human Origin: No
Does the device contain Human Blood or its components: No
Does the device consist of: Single product only
Does the device contain material or ingredients of Animal Origin rendered non-viable: No
Does any component in the procedure, kit or system contain material or ingredients of Animal Origin rendered non-viable: No
Is the device medicated: No
Is the device formulated: No
Does the product contain a medicine that is supplied separately in the Australian Market: No
Does the product contain a medical device which incorporates a medicine as an integral part and that has an action ancillary to the device: No
Is the device software or does it incorporate software?

Application Summary	
Application ID:	DV-2010-DA-01806-3
Submission ID:	DA-2010-00874-7
Sponsor's own reference:	Richard Wolf Morcellation/Shaver system
Application for:	Medical Device - Included
Will you be applying for listing of this product or procedure in	◯ Yes ◯ No

the Medicare Benefit Schedule (MBS)?	
Will you be applying for listing of this product on the Prosthesis List?	◯ Yes ◯ No
Will you be applying for listing of this product on the Co-dependent or hybrid technology application list?	◯ Yes ◯ No
Sponsor name:	Endocorp Pty Ltd
Sponsor ID:	19378
Agent name:	
Contact details:	s22
Contact email:	s22 @gsenterprises.com.au
Is this application supported by EU MDR/IVDR certification?	

Manufacturer Information	
Manufacturer's evidence:	040714-WEBE-62V6FU :Richard Wolf GMbH Goto
Manufacturer name:	Richard Wolf GmbH (Germany)[16344]
Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Assessment body:	Dekra Certification GmbH [0124]
GMDN code:	Tissue morcellation system[46729]
GMDN description:	An assembly of devices used to mechanically cut (slice), core (cut a hole into), peel (remove surface), and extract selected tissue from the body (a process known as morcellation), typically during laparoscopic surgery (e.g., for tumour or fibroid removal). It typically consists of a handpiece (high-speed rotating blade and holder) for tissue resection and extraction, a mains electricity (AC-powered) control unit that drives the speed/torque of the handpiece blade, a remote drive cable to connect the handpiece with the control unit, and a foot-switch.
Intended purpose:	Intended to morcellate and remove tissue (bone, cartilage, soft tissue) in endoscopic/surgical procedures such as arthroscopy, thoracic surgery, sinus surgery (FESS),urological and Gynaecological procedures

Device Category Terms	
Device category 1:	Reusable devices

Attached Documentation

History
24/02/2010 3:01:51 PM Approved. Review Completed - Accepted, 24/02/2010)

Record		Date	
Fee:	790	Date Paid:	14/02/2010
		Date Decision:	24/02/2010

Start Dates		Finish Dates		Working Days
Application Received	11/02/2010	Payment Received	14/02/2010	1
Payment Received	14/02/2010	Application Decision	24/02/2010	8
			Total Working Days	9

CERTIFICATE

for the

Quality Assurance System

As a notified body of the European Union (Reg. No. 0124) DEKRA Intertek Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

Richard Wolf GmbH

Pforzheimer Straße 32 • D-75438 Knittlingen

Approval is based on the result of the certification audit with report number 50593-Z3-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	10.07.1995	Date of the last recertification:	06.07.2005
This certificate is valid until:	05.07.2010	Certificate-registration No.:	50593-16-01 English version

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DEKRA Intertek Certification GmbH
Stuttgart, 01.07.2005

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Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

DEKRA
INDUSTRIAL

Annex to the Certificate 50593-16-01 dated 01.07.2005

English version

Revision status: 0 Date: 06.07.2005 Page 1 of 3

Devices/device categories included in the certificate

NON-ACTIVE DEVICES - Class IIa, Annex IX of Directive 93/42/EEC :

Endoscopes and Accessories

Adaptors, applicators, aspirators, attachments

Bridges

catheters, clip applicators, cannulas, connectors, caps, carrier, containers connecting tubes

drills, dilatators, dissectors

ejectors, elevators, endoscopes (telescopes) rigid and flexible

forceps, filter housing

graspers

handles, holders, humidifiying chambers

inserts, issufflation tubes, irrigator unit, intubation tubes

light rods, laser protector

morcellators, mediastinoscope

needles

obturators

probes, ports

respiration jet, raspators, reducer sleeves, reamers

spring elements, suction-irrigation instrument, sleeves, sheath, stop cocks, shafts

trocar sleeves, tubes, taps, tubing, tube sets

uterus manipulators

valves

working- and multifunction elements / instruments

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English version

NON-ACTIVE DEVICES - Class IIa, Annex IX of Directive 93/42/EEC:

Sterile products

Catheter, filters, tube sets, cannulas

NON-ACTIVE DEVICES - Class IIb, Annex IX of Directive 93/42/EEC:

Implantable medical devices and sterile products

Clips, suture

NON-ACTIVE DEVICES - Class III, Annex IX of Directive 93/42/EEC:

Implantable medical devices and sterile products

Hulka Clips, glass capillaries

ACTIVE DEVICES - Class IIa, Annex IX of Directive 93/42/EEC:

Endoscopes and Accessories

Power cutters and burrs:
Abraders, incisors, planers, blades, cutters, burrs, resectors, acromionizers, whiskers, edgers, arthroburrs

Sterile products

Power cutters and burrs:
Abraders, incisors, planers, blades, cutters, burrs, resectors, acromionizers, whiskers, edgers, arthroburrs

Endoscopic Units and accessories

Sterile water filter unit, suction-irrigation pumps, devices for motorised instruments and accessories, disinfectors, gas humidifier

Surgical and dental units and accessories

Devices with irrigation for motorized instruments and accessories:
drills, burrs, saws, dermatoms and scalpels

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ACTIVE DEVICES - Class IIb, Annex IX of Directive 93/42/EEC:

Endoscopic Units and accessories

Insufflators (Pneu or Pneu Devices), pumps (smoke and liquid evacuation), lithotripsy units (electrohydraulic, ultrasound), sonotrodes, transducers, highfrequency electrosurgery units and instruments (monopolar/bipolar), control computers

ACTIVE DEVICES - Class IIb, Annex IX of Directive 93/42/EEC:

Products for therapy with extracorporally generated shock waves and pressure pulses

Piezoson, Piezolith, Therapy sources ESWL (Extracorporeal shock wave lithotripsie) / ESWT (Extracorporeal shock wave therapy)

Sterile products

Probes

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