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Manufacturer Evidence

Status : Approved

Certificate change history

Version 1: Accepted - Note to Assessor - The scope of the EC Certificate has been restricted by the Notified body to a range of devces as specified. Manufacturer's evidence processed as per 1/7/08. GMDN codes, intended purpose & classification will be assessed at point of application. AE&CS has informed sponsor of accepted Manufacturers evidence.
[redacted]

Date received :	11/01/2011
Certificate printed :	No

Variation to Evidence ID: DV-2009-MC-03132-3

Notification details

Evidence identifier:	DV-2009-MC-03132-3
Submission identifier:	DM-2011-00164-7
Version number:	2
Sponsor's own reference:	Alpine Medical Shenzhen Ant Hi-Tech Ind ME

Sponsor details

Agent name:	Right Time Business Pty Ltd
Sponsor name:	Medical Industries Australia
Contact details:	[redacted]

Certification details

Manufacturer name:	Shenzhen Ant Hi-Tech Industrial Co Ltd (China - Peoples Republic of)[51531]
Manufacturer address as on certification:	Building 11 Lishan Industrial Park Xinghai Avenue Nanshan District Shenzhen S of S [169992]

Type of product:

○ This certification is to support an application for an in vitro diagnostic medical device (IVD)
● This certification is to support an application for a medical device that is not an in vitro diagnostic medical device (IVD)

Certificate issued under:	Council Directive 93/42/EEC (MDD)
Conformity assessment procedure:	Schedule 3 Part 1 (Annex II)
Source of certification:	TUV SUD Product Service GmbH [0123] Lookup
Certificate number:	G1 10 08 56846 012
Certificate issue date: (dd/mm/yyyy)	18/12/2006
Certificate expiry date: (dd/mm/yyyy)	15/11/2015
Certificate re-issue date: (dd/mm/yyyy)	
Restrictions on scope:	High Pressure Syringes,Manifold, Pressure Connecting Tube, Introducer Set, Ui Catheter Set, Invasive Blood Pressure Transducer, Positive Needlefree Connect

Restriction on conformity assessment procedure:
Full Quality Assurance Certificate.
Note: For Class III a Design Examination Certificate must be submitted with the Device Application.

Attached documentation:

Attached documents — Updated EC Certificate - Shenzhen Ant Hi-Tech Ind CE 2015.pdf

Supporting documents:

#	Document Type	Description	Method

Related Active ARTG Entry Information:

227703	Medical Industries Australia - Connector, tubing
227704	Medical Industries Australia - Tubing, radiographic procedure

History

CN=Ian Carroll/OU=TGA/O=Health

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 10 08 56846 012

Manufacturer:

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
Building 11, Lishan Industrial Park
Xinghai Avenue
Nanshan District
518052 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

EC-Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg
GERMANY

Product Category(ies):

High Pressure Syringe, Manifold, Pressure Connecting Tube, Introducer Set, Ureteral Stent Set, Drainage Catheter Set, Disposable Pressure Transducer, Positive Needlefree Connector

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: BJ1081107

Valid until: 2015-11-15

Date, 2010-11-16

[redacted]

TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

ZERTIFIKAT ◆ CERTIFICATE ◆ 證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

EC-Certificate
Full Quality Assurance System
(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)
No. G1 10 08 56846 012

Facility(ies):

Shenzhen Ant Hi-Tech Industrial Co., Ltd.
Building 11, Lishan Industrial Park, Xinghai Avenue, Nanshan District, 518052 Shenzhen, PEOPLE'S REPUBLIC OF CHINA