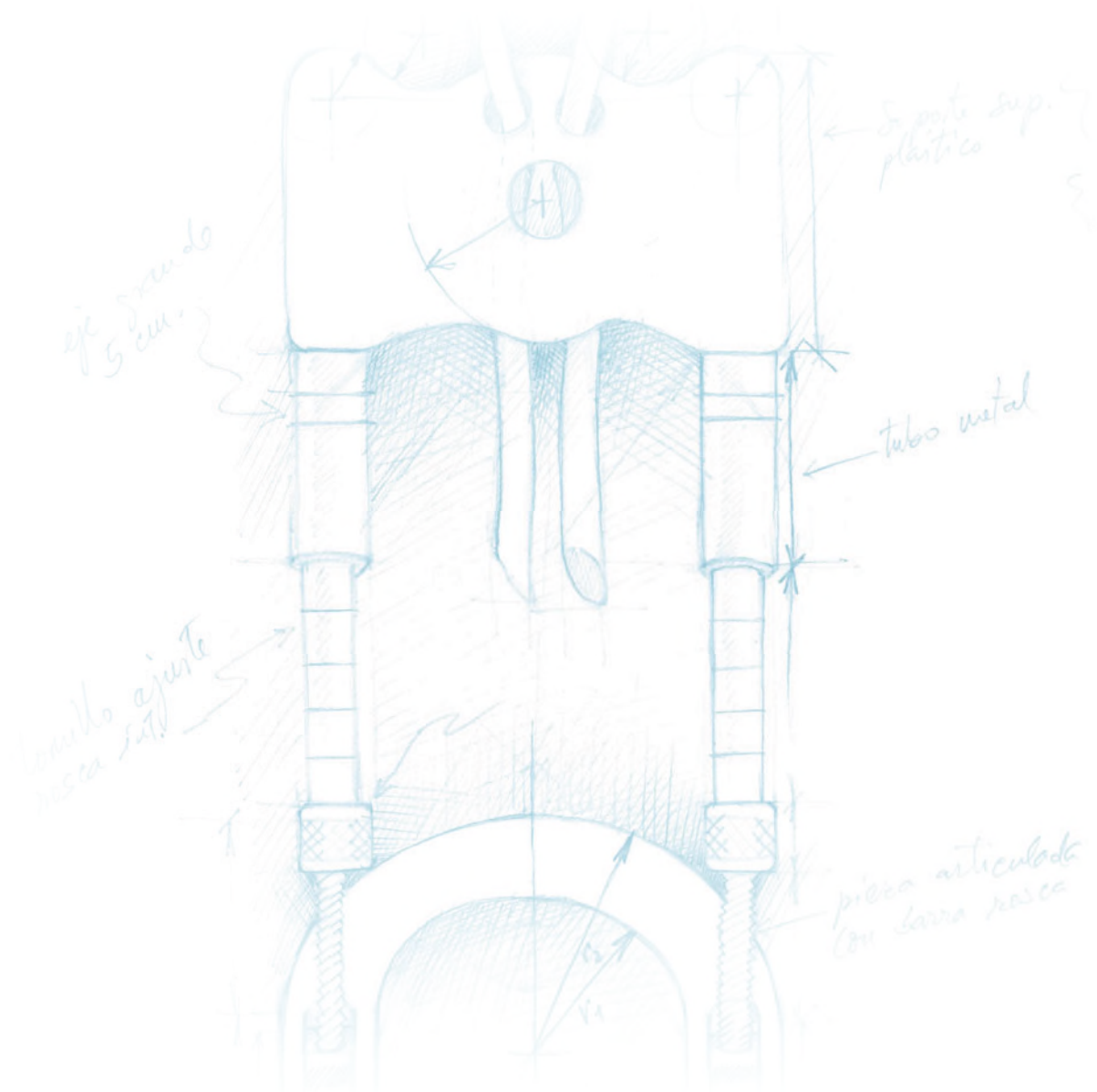
LICENSES DOSSIER

andro penis®



Andromedical Licenses Dossier for Andropenis®

MEDICAL & QUALITY GUARANTEES

- Health Manufacturing License
- Declaration of Conformity and Free Sale
- ISO 9001:2008
- ISO 13485:2003

HEALTH CERTIFICATES

- CE Declaration of Conformity
- USA FDA Registration
- Canada Health Certificate
- Australia Health Certificate
- Russia Health Certificate
- Saudi Arabia Health Certificate

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD

agencia española de medicamentos y productos sanitarios

PS/MS/CM

LICENCIA SANITARIA PREVIA DE FUNCIONAMIENTO DE INSTALACIÓN DE PRODUCTOS SANITARIOS

Haciendo uso de las atribuciones que me están conferidas, de conformidad con lo dispuesto en el Real Decreto 1275/2011, de 16 de septiembre, por el que se crea la Agencia estatal "Agencia Española de Medicamentos y Productos Sanitarios" y se aprueba su estatuto y en el artículo 9.1 del Real Decreto 1591/2009, de 16 de octubre, por el que se regulan los productos sanitarios a propuesta del Departamento de Productos Sanitarios, y condicionada la autorización al informe favorable del Área de Sanidad de la Delegación del Gobierno en Madrid, C/ Francisco Silvela, 57, 28028, Madrid

Emito nueva LICENCIA por: REVALIDACIÓN, TRASLADO DE INSTALACIONES, MODIFICACIÓN DE ACTIVIDADES CONCERTADAS Y AMPLIACIÓN DE PRODUCTOS FABRICADOS
Fecha de LICENCIA inicial: 04-04-2003
Fecha de la última actuación modificación: 7-03-2011

DENOMINACIÓN DE LA EMPRESA **ANDROMEDICAL, S.L.**	**NÚMERO DE LICENCIA** **5144-PS**
CIF/NIF B82545096	
DOMICILIO C/ NORIAS, 80, PLANTA 2, OFICINA A, 28221, MAJADAHONDA, MADRID	
ACTIVIDAD PROPIA FABRICACIÓN EN SERIE E IMPORTACIÓN DE PRODUCTOS SANITARIOS	
ACTIVIDADES CONCERTADAS VER ANEXO	
TIPO DE PRODUCTO – FABRICACIÓN: EXTENSORES PENEALES, KITS DE ACCESORIOS PARA LOS EXTENSORES PENEALES, MONITORES DE RIGIDEZ AXIAL DE ERECCIÓN – IMPORTACIÓN: BOMBA DE VACÍO PARA TRATAMIENTO DE DISFUNCION ERECTIL	
TÉCNICO RESPONSABLE D. EDUARDO ANTONIO GÓMEZ DE DIEGO **TITULACIÓN** LICENCIADO EN CIRUGÍA Y MEDICINA	

Esta licencia queda condicionada al informe favorable de la visita de inspección, otorgándose hasta el 12 de noviembre de 2018. En caso de informe desfavorable se iniciarían los trámites oportunos para la revocación de la misma. Podrá ser revalidada a solicitud del interesado, formulada con anterioridad al último trimestre de su vigencia.

MINISTERIO DE SANIDAD, SERVICIOS SOCIALES E IGUALDAD agencia española de medicamentos y productos sanitarios

Madrid, a 12 de noviembre de 2013
LA DIRECTORA DE LA AGENCIA ESPAÑOLA DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Belén Crespo Sánchez-Eznarriaga

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 902-1013-22
FAX: 91 822 50 10

DEPARTMENT OF HEALTH, SOCIAL SERVICES AND EQUALITY

Spanish department of medicines and medical devices

PS/MS/CM

ADVANCE MEDICAL LICENSE FOR THE OPERATION OF FACILITIES PRODUCING MEDICAL DEVICES

By the powers vested in me, in accordance with Royal Decree 1275/2011, of the 16th September, establishing the State Department entitled "Spanish Department of Medicines and Medical Devices" and approving its by-law, and with Article 9 of Royal Decree 1591/2009, of the 16th October, regulating medical devices on the proposal of the Department of Medical Devices, and with authorisation on condition of a favourable report by the Health Department of the Government Office of Madrid, C/ Francisco Silvela, 57, 28028, Madrid

I hereby issue this new LICENSE due to: RENEWAL, CHANGE OF LOCATION OF THE FACILITIES, MODIFICATION OF AGREED ACTIVITIES AND AN INCREASE IN THE RANGE OF PRODUCTS MANUFACTURED
Date of initial LICENSE: 4th April 2003
Date of last modification: 7th March 2011

NAME OF COMPANY **ANDROMEDICAL, S.L.**	**LICENSE NUMBER** **5144-PS**
CIF/NIF (Spanish Tax Code) B82545096	
ADDRESS C/ NORIAS, 80, PLANTA 2, OFICINA A, 28221, MAJADAHONDA, MADRID	
PRINCIPAL ACTIVITY MASS PRODUCTION AND IMPORTATION OF MEDICAL DEVICES	
ACTIVITIES UNDER AGREEMENT WITH OTHER COMPANIES SEE ANNEXE	
TYPE OF PRODUCT - MANUFACTURE: PENILE EXTENDER DEVICES, ACCESSORY KITS FOR THE EXTENDER DEVICES, MONITORS FOR MEASURING THE AXIAL RIGIDITY OF ERECTIONS - IMPORTATION: VACUUM PUMPS FOR THE TREATMENT OF ERECTILE DYSFUNCTION	
TECHNICIAN IN CHARGE MR. EDUARDO ANTONIO GÓMEZ DE DIEGO **QUALIFICATION** BACHELOR OF MEDICINE AND OF SURGERY	

This license is granted on the condition of a favourable report resulting from the inspection visit, and is valid until the 12th November 2018. In the event of an unfavourable report being issued, proceedings will be initiated to revoke the license. The interested party may request the renewal of the license by providing prior notice during the final three months of its period of validity.

Stamp:
[DEPARTMENT OF HEALTH, SOCIAL SERVICES AND EQUALITY
Spanish department of medicines]

Madrid, on the 12th November 2013
DIRECTOR OF THE SPANISH DEPARMENT OF MEDICINES AND MEDICAL DEVICES

[Signature]

Belén Crespo Sánchez-Eznarriaga

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 902-1013-22
FAX: 91822 50 10

LETICIA DE AGUSTÍN FERNÁNDEZ
TÉRPRETE JURADO INGLÉS-ESPAÑOL
N.I.F. 11844460 N
C/ Peñalara Y, Portal 3, 1º A
28224 Madrid
Tel.: (+34) 677 392 165
E-mail: lagusa@globalmail.es

Establishment Registration & Device Listing

New Search | Back To Search Results

Establishment:
ANDROMEDICAL SL
Norias 80, 2 A
Majadahonda Madrid, Comunidad De, SPAIN 28221
Registration Number: 3006891790
Status: Active
Date Of Registration Status: 2015

Owner/Operator:
ANDROMEDICAL SL
Norias 80
2 A
Majadahonda, ES-M SPAIN 28221
Owner/Operator Number: 10024070

Official Correspondent:
Eduardo Gomez De Diego
Norias 80
2 A
Majadahonda, ES-M SPAIN 28221
Phone: 34-91-6381899

US Agent:
Mr. Rene Van De Zande
Emergo Group, Inc.
816 Congress Ave Ste 1400
Austin , TX 78701
Phone: 512 3279997 Ext
Fax: 512 3279998
Email: Usagent@emergogroup.com

Page Last Updated: 05/11/2015
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

MINISTERIO
DE SANIDAD, SERVICIOS SOCIALES
E IGUALDAD

agencia española de
medicamentos y
productos sanitarios

DEPARTAMENTO DE
PRODUCTOS SANITARIOS

PS/DP/MST 505/2013-CERT.

Dª Mª del Carmen Abad Luna, Jefe del Departamento de Productos Sanitarios de la Agencia Española de Medicamentos y Productos Sanitarios,

CERTIFICA:

Que la empresa ANDROMEDICAL, S.L., con sede en la C/ NORIAS 80, PLANTA 2, OFICINA A, 28221 MAJADAHONDA (MADRID), cuenta con licencia de funcionamiento como fabricante e importador de productos sanitarios, en aplicación de la legislación española, correspondiéndole el Nº 5144-PS.

Que entre los productos fabricados se encuentran los denominados

- **ANDROERECTEST**
- **ANDROEXTENDER**
- **ANDROPENIS GOLD**
- **ANDROPEYRONIE**
- **ANDROPENIS MINI**

Que entre los productos importados, se encuentra el denominado:

- **ANDROVACUUM**

que cuentan con marcado CE, en aplicación de la Directiva 93/42/CEE, relativa a los productos sanitarios, lo que permite su comercialización en España y en el resto de países de la Unión Europea, no existiendo trabas para su exportación.

Y para que conste y surta los efectos oportunos ante QUIEN CORRESPONDA, lo firmo en Madrid a veintiocho de noviembre de dos mil trece.

agencia española de
medicamentos y
productos sanitarios
Departamento de Productos Sanitarios

CORREO ELECTRONICO
sgps@aemps.es

C/ CAMPEZO, 1 – EDIFICIO 8
28022 MADRID
TEL: 91 822 52 61
FAX: 91 822 52 89

MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY
Spanish Agency of Medicines and Healthcare Products.

DEPARTMENT OF HEALTHCARE PRODUCTS

PS/DP/MST 505/2013-CERT.

Mª del Carmen Abad Luna, Head of the Department of Healthcare Products of the Spanish Agency of Medicines and Healthcare Products,

HEREBY CERTIFIES:

That the company ANDROMEDICAL, S.L. with head office at C/ NORIAS 80, 2nd floor, Office A, 28221 MAJADAHONDA (MADRID), holds operating licence as manufacturer and importer of healthcare products, in application of Spanish Law, corresponding to No. 5144-PS.

That the following are included among the products which it manufactures:

- **ANDROERECTEST**
- **ANDROEXTENDER**
- **ANDROPENIS GOLD**
- **ANDROPEYRONIE**
- **ANDROPENIS MINI**

That the following are included among the products which it imports:

- **ANDROVACUUM**

That they have CE marking, in application of the EC Directive 93/42/EEC, relating to the healthcare products, which permits their commercialisation in Spain and other countries in the European Union, and there are no impediments for their export.

In witness whereof, for the appropriate effects for WHOMSOEVER IT MAY CONCERN, I sign this certificate in Madrid, on the twenty-eight of November in the year two thousand and thirteen.

E-MAIL
sgps@aemps.es

Signature: (ILLEGIBLE)

Stamp: Spanish Agency of Medicines and Healthcare Products
Department of Healthcare Products

C/ CAMPEZO, 1 – EDIFICIO
28002 MADRID
Tel: 91 822 52 61
FAX: 91 822 52 89

Don Juan Amor Fernández, Intérprete Jurado de Inglés, certifica que la que antecede es traducción fiel y completa al inglés de un documento redactado en español.

I the undersigned Juan Amor Fernández, sworn translator for the English Language do hereby certify that the foregoing is a true and faithful version of the original Spanish document hereunto attached.

JUAN AMOR FERNANDEZ * INTERPRETE JURADO DE ALEMAN, INGLES, ITALIANO, PORTUGUES, CATALAN * FRANSENA III PORTAL B 2º IZQ 30880 AGULAS-MURCIA 27595817

Aguilas (Murcia) Spain, 17th December 2013

Certificate ES15/19060

The management system of

ANDROMEDICAL, S.L.

C/ Norias, 80, 2º Piso, Oficina A
28021 Majadahonda, Madrid. Spain

has been assessed and certified as meeting the requirements of

ISO 9001:2008

For the following activities

Design, manufacturing, distribution and sales of medical devices for the treatment of penile dysfunctions.

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2008 requirements may be obtained by consulting the organisation

This certificate is valid from 3 December 2015 until 2 December 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 9 October 2018
Issue 1. Certified since 3 December 2015

Authorised by

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-8 01 0614

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Certificate ES15/19061

The management system of

ANDROMEDICAL, S.L.

C/ Norias, 80, 2º Piso, Oficina A
28021 Majadahonda, Madrid. Spain

has been assessed and certified as meeting the requirements of

ISO 13485:2003
EN ISO 13485:2012

For the following activities

Design, manufacturing, distribution and sales of medical devices for the treatment of penile dysfunctions.

This certificate is valid from 3 December 2015 until 2 December 2018
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 9 October 2018
Issue 1. Certified since 3 December 2015

Authorised by

UKAS MANAGEMENT SYSTEMS
0005

SGS United Kingdom Ltd Systems & Services Certification
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 13485-2 1114

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C/Proción 7-28023-MADRID-SPAIN. C.I.F B 82545096
Tel: +34902 305 405 - Fax: +34 91 679 6019
www.andromedical.com

CE DECLARATION OF CONFORMITY

Eduardo Antonio Gómez de Diego, in the name and on behalf of Andromedical SL a medical company, with CIF number B-82545096 and place of **business in Madrid, Procion Street 7, CP 28023, manufacturer of the non sterile Medical Device Type I Andropenis®, for the indications of treatment of Peyronie's disease and correction of other congenital penile curvatures; treatment of male hypogonadism with micropenis or small penis; aesthetic treatment for penile lengthening and thickening; post-surgical treatment of some urological surgeries (prostatectomy, penile surgery, trauma, etc.)** to avoid penile shortening due to scar retraction, hereby,

DECLARES

Under his sole responsibility, that the products set out below commercially known as:

Andropenis Gold
Andropenis Mini
Androextender
Andropeyronie
Androsurgery

To which this declaration is related to, are manufactured under the requirements of the European Council Directives 1993/42 and 2007/47 on Health Products transposed into Spanish legislation by RD 1591/2009 of October 16th on the approximation of the laws of Member States regarding non Invasive Medical Devices.

The manufacturer, hereby, bears full responsibility for the production conformity to the requirements Stated in the declaration.

Madrid, October 19th of 2011
Dr. Eduardo Gómez de Diego

Regulatory Affairs Manager

CERTIFICATE ISO 13485:2003
MD 99155

CERTIFICATE ISO 9001:2008
FS 81458

C/Proción 7-28023-MADRID-ESPAÑA. C.I.F B 82545096
Tel: +34902 305 405 - Fax: +34 91 679 6019
www.andromedical.com

CE

Eduardo Antonio Gómez de Diego, en nombre y representación de Andromedical S.L, entidad mercantil con CIF número B-82545096 y sede en Madrid, **Calle Proción 7, C.P 28023, fabricante del producto sanitario Tipo I, no estéril y sin función de medición, Andropenis®** destinado a las indicaciones de tratamiento de la enfermedad de Peyronie y corrección de curvaturas peneanas congénitas; tratamiento del hipogonadismo masculino con micropene o pene pequeño; tratamiento estético de alargamiento y engrosamiento del pene; tratamiento post-quirúrgico en algunas cirugías urológicas (prostatectomía, cirugías peneanas, traumatismos, etc.) para evitar el acortamiento del pene debido a la retracción cicatricial; tratamiento de la disfunción eréctil para la mejora de la rigidez peneal para realizar el acto sexual, a través del incremento del tamaño (en longitud y perímetro) y de la corrección de la morfología.

DECLARA

Bajo su entera y exclusiva responsabilidad, que los productos de nombre comercial que se exponen a continuación:

Andropenis Gold
Andropenis Mini
Androextender
Andropeyronie
Androsurgery

A los que esta declaración refiere, están fabricados conforme a los requisitos exigidos por las Directivas del Consejo Europeo 1993/42 y 2007/47 sobre Productos Sanitarios, transpuestas a la legislación española mediante el Real Decreto 1591/2009 de 16 de octubre.

Madrid a 19 de octubre de 2011
Dr. Eduardo Gómez de Diego

Responsable Técnico

CERTIFICATE ISO 13485:2003
MD 99155

CERTIFICATE ISO 9001:2008
FS 81458

Establishment Registration & Device Listing

New Search | Back To Search Results

Proprietary Name:	Andro-extender; Andro-penis; Andro-peyronie; Androextender; Andropenis; Andropenis Gold; Andropenis Mini; andropeyronie
Classification Name:	DEVICE, EXTERNAL PENILE RIGIDITY
Product Code:	LKY
Device Class:	2
Regulation Number:	876.5020
Medical Specialty:	Gastroenterology
Registered Establishment Name:	ANDROMEDICAL SL
Registered Establishment Number:	3006891790
Owner/Operator:	ANDROMEDICAL SL
Owner/Operator Number:	10024070
Establishment Operations:	Manufacturer

Health Canada / Santé Canada

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments

Licence Number **6670** Numéro de la licence

Medical Device Establishment Licence

Licence d'établissement pour les instruments médicaux

ANDROMEDICAL, S.L.

CI PROCION 7
MADRID
SPAIN
28023

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	No / Non	No / Non	Yes / Oui
Class II / Classe II	No / Non	No / Non	
Class III / Classe III	No / Non	No / Non	
Class IV / Classe IV	No / Non	No / Non	

Attestation made : **Attestations faites :**

The establishment has documented procedures in place in respect of:		L'établissement a mis en oeuvre une procédure écrite concernant:
• distribution records	[Y]	• les registres de distribution
• complaint handling	[Y]	• les plaintes
• recalls	[Y]	• les rappels
• mandatory problem reporting	[Y]	• rapports d'incident obligatoires
• handling, storage, delivery	[N]	• la manutention, le stockage, la livraison
• installation	[N]	• l'installation,
• corrective action	[N]	• les mesures correctives
• servicing	[N]	• l'entretien

Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2015-06-09

Minister of Health Ministre de la santé	Countersigned: Director General, Health Products & Food Branch Inspectorate or delegated authority Contresigné par: Directeur Général, Inspectorat de la Direction générale des produits de santé et des aliments ou autoritée déléguée Etienne Ouimette

This licence is the property of the Health Products & Food Branch Inspectorate and must be returned upon demand.
Cette licence appartient au programme d'Inspectorat de la Direction générale des produits de santé et des aliments et doit être retournée sur demande

Canada

Health Products and Food Branch Inspectorate / Inspectorat de la Direction générale des produits de santé et des aliments
Establishment Licence
Licence d'établissement
Health Canada / Santé Canada
Canada

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

ARTG Certificate

Issued to

Emergo Asia Pacific Pty Ltd

for approval to supply

Emergo Asia Pacific Pty Ltd - Penile traction splint

ARTG Identifier	**154288 Class 1**
ARTG Start date	**04/08/2008**
Product Category:	**Medical Device Included Class 1**
GMDN	**46340**
GMDN Description	**Penile traction splint**
Intended Purpose	**The Andropenis? is intended for correction of penile curvatures without surgery, treatment of Peyronie?s Disease, as well as post surgical treatment of penile lengthening surgery, and after plastic and reconstructive surgeries of the penis.**

Manufacturer(s) Details	Address	Manufacturing steps
Andromedical SL	Calle Procion 7 Madrid, , 28023	

ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41FN of the Therapeutic Goods Act 1989.
- The standard conditions that are imposed under section 41FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.
- For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.
- Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.
- The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.
- The sponsor shall provide to the Director, Office of Devices, Blood and Tissues, Therapeutic Goods Administration, three consecutive reports which include information of a kind specified in Regulation 5.8 that arises during the reporting period, concerning Class III, Class AIMD or implantable Class IIb medical devices. The reporting period for the first report commences on the date of inclusion and is to be at least a period of six months but not more than 18 months ending on 1 October. For subsequent reports the reporting period is 12 months ending on 1 October.
- Where a medical device included in the Register, contains a substance which is included in the Fourth Schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.
- A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided by the manufacturer.

Products covered by this Entry

1. Penile traction splint

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

No specific indications have been recorded against this entry.

END OF CERTIFICATE

ARTG Certificate

Produced 02.12.2008 at 03:50:08 EST

The details contained in this copy of the ARTG Certificate reflect the information held at the nominated date and time of printing.
The currency and accuracy of the details can be confirmed at www.ebs.gov.au.

ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗДРАВООХРАНЕНИЯ
И СОЦИАЛЬНОГО РАЗВИТИЯ

FEDERAL SERVICE OF HEALTH CARE AND SOCIAL DEVELOPMENT CONTROL

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ
REGISTRATION CERTIFICATE

ФС №2006/603

ДУБЛИКАТ

ДЕЙСТВИТЕЛЬНО с **3 мая 2006 года** до **3 мая 2016 года**

ИЗДЕЛИЕ МЕДИЦИНСКОЙ ТЕХНИКИ

Устройство для увеличения размеров и коррекции изгибов полового члена Andro-Penis (Faltronik).

ПРОИЗВОДИТЕЛЬ ***ANDROMEDICAL, S.L., Испания.***

ЗАРЕГИСТРИРОВАНО В РОССИЙСКОЙ ФЕДЕРАЦИИ
ВНЕСЕНО В ГОСУДАРСТВЕННЫЙ РЕЕСТР
ИЗДЕЛИЙ МЕДИЦИНСКОГО НАЗНАЧЕНИЯ И МЕДИЦИНСКОЙ ТЕХНИКИ

Государственная регистрация предусматривает надзор за производством
в целях обеспечения безопасности, качества, эффективности
зарегистрированных изделий медицинского назначения и медицинской техники

Руководитель Федеральной службы
по надзору в сфере здравоохранения
и социального развития ***Р.У. Хабриев***

Дубликат выдан 18 декабря 2006 года

Kingdom of Saudi Arabia
Saudi Food & Drug Authority
Medical Devices Sector
Registration & licensing Department

المملكة العربية السعودية
الهيئة العامة للغذاء والدواء
قطاع الأجهزة والمنتجات الطبية
إدارة التسجيل والتراخيص

رخصة منشأة أجهزة ومنتجات طبية
Medical Device Establishment License

Saudi Food and Drug Authority certifies that:

تشهد الهيئة العامة للغذاء والدواء بأن:

Allied Technologies Est.

Sharbatly Center,
Hail St., Entrance 2,
2nd floor, Office 19

Is licensed by the Saudi Food and Drug Authority to operate in the field of medical devices pursuant to the Medical Device Interim Regulation for the activities defined in the license.

مُرخصة لديها للعمل في مجال الأجهزة والمنتجات الطبية بموجب لائحة رقابة الاجهزة والمنتجات الطبية لممارسة الأنشطة المحددة في هذه الرخصة.

License Number :	09090015	09090015	رقم الرخصة :
Issuing Date :	24/10/2009	1430/11/5	تاريخ الإصدار :
Expiry Date :	12/10/2010	1431/11/4	تاريخ الانتهاء :
Establishment Category :	C	ج	درجة تصنيف المنشأة :
Establishment Activity :	Distribution & Importation	استيراد وتوزيع	نشاط المنشأة :

مدير إدارة التسجيل والتراخيص
Director of Registration & Licensing Department

00015