HYDRUMEDICAL

COMPANY PRESENTATION

Projects and investments .

March 2021

Hydrustent SA

Catarina Sepúlveda

Project Manager

csepulveda@hydrumedical.pt

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EXECUTIVE SUMMARY .

HydrUStent SA was born in 2016 with the mission to create, develop and manufacture biodegradable medical devices and help building a sustainable world.

We have been successfully developing innovative medical devices for urology and gastroenterology. Our patented technology allowed us to create the first 100% biodegradable hydrogel-based ureteral stent (**HydrUStent™**). After 4 years of many accomplishments and hard work, the company's name changed to **HYDRUMEDICAL** as our range of projects has broadened. We have embraced new projects that have led us to develop innovative medical technologies in new medical areas. Furthermore, as a rapid reaction to the market needs in the pandemic situation we live, HYDRUMEDICAL launched a medical infection control line, a full range of disinfectant products that will provide a safe environment in healthcare and near-patient environments.

We have strongly invested in our facilities, namely in strengthening our skills through cutting edge equipment that allows us to increase our development and manufacturing capabilities: a 12m2 certified clean room (ISO6), mixer (medical devices coating development), CO2 supercritical fluid equipment and a production site with automated filling and encapsulate liquid machine, and labelling machine (from 50 ml to 1L).

2016.

Company founded

Pre-clinical studies

HYDRUSTENT

2018.

€ 2 M Private investment

2019.

HydruSensor
Technology

Scale-up

HYDRUSTENT

Certification
ISO 13485, ISO 9001 and NP 4457

2020.

Clean Room
ISO 6 certified

Rebranding

HYDRUMEDICAL

Production Site
Automated filling and encapsulation labelling machine 50mL to 1 L

Launching
Infection Control Line

2021.

Hydrustoma C3
Colostomy technology
Launching

HYDRU®LUB
Sterile lubricant
HYDRU®AQUA
Sterile catheter inflation solution
Launching

HYDRU TEAM .

Multidisciplinar and Experienced team

Large Medical network with KOLs

Biomedical Cluster

Estevão E. Lima
Chief Medical Officer

Alexandre Barros
CEO & Business Development

Rui L. Reis
President & Chairman

Liliana Gonçalves
Regulatory Affairs Manager

Pedro Bragança
Chief Financial Officer

Sara Neves
Innovation Analyst

Catarina Sepúlveda
Marketing Analyst

Ana Filipa Ribeiro
Administrative Assistant

André Castro
Sales Manager

IPCA - Polytechnic Institute of Cávado and Ave

2Ai - Applied Artificial Intelligence Laboratory

University of Minho
I3Bs - Research Institute for Biomaterials, Biodegradables and Biomimetics

CeNTI - Centre for Nanotechnology and Smart Materials

We are part of an ecosystem where medical engineers, doctors and researchers join efforts to develop the most advanced technologies in the medical device area, including medical software and electronics development.

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Hydrumedical Products & Technologies .

Urology .	4 Products
Stoma Care .	1 Product
Infection Control Line .	4 Products

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Urology.

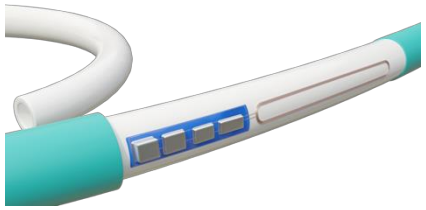
HydrUStent™

Biodegradable Ureteral Stent intended to be used to temporary drain obstructed ureter. The patented structural hydrogel have a homogenous degradation.

Patented Product

HYDRU® AQUA

Sterile solution for catheter inflations for indwelling Balloon catheters.



HydrUSensor™

Pressure sensor ureteral stent, a wireless intrarenal and intravesical device for real-time urological pressure measurement.

Patented Product

HYDRU® LUB

Sterile lubricant without any active substance

HYDRUSTENT

NON-DEGRADABLE IS SO 20TH CENTURY®

Co-financed by

NORTE 2020 | PORTUGAL 2020 | UNIÃO EUROPEIA Fundo Europeu de Desenvolvimento Regional

Urology.

First Biodegradable Ureteral Stent intended to be used to temporary drain obstructed ureter. The patented structural hydrogel has a homogenous degradation.

Market launch by late 2022

Patented Product

Business

Global Ureteral Stents Market to Surpass US$ 564.4 Million By 2026

10 July 2019, 14:34 WEST

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Global Ureteral Stents Market to Surpass US$ 564.4 Million By 2026

Business Wire

SEATTLE -- July 10, 2019

According to Coherent Market Insights, the global ureteral stents market was valued at US$ 359.9 million in 2018, and is projected to exhibit a CAGR of 5.8% during the forecast period (2018 - 2026).

Key Trends and Analysis of the global Ureteral Stents Market:

Presence of key players who are focused on developing products that can bypass limitations such as infection, discomfort, and other problems, is contributing significantly to the market growth. For instance, in January 2019, Q Urological Corporation developed an aqueous hydrogel biomaterial, pAguamedicina, and patented processing method for production of very high aqueous content to produce 100% hydrogel catheters and stents.

Request Sample Copy of this Report @ https://www.coherentmarketinsights.com/insight/request-sample/2172

In addition, technological innovation in urology products are providing an immense opportunity for the manufacturer to produce technologically advanced ureteral stents. For instance, in June 2018, HydrUStent has developed the Hydrustent Biodegradable Ureteral Stent from its patented material, which prevents the need for a second surgery for stent removal, and also prevents bacterial colonization and biofilm formation which leads to infection.

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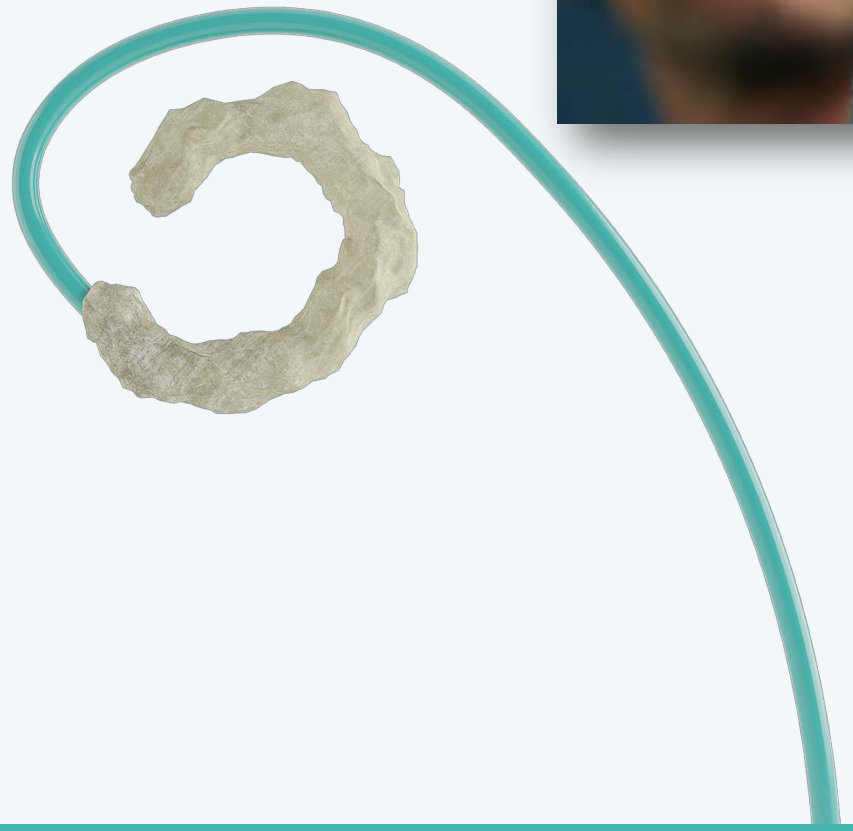
NON-DEGRADABLE IS SO 20TH CENTURY®

Urology.



Do you want to have this in your body ?

100% of **bacterial infection** after 30 days;

Require a **second surgery** for stent removal;

Source : Stone Treatment Device Market, Report from iData Research Inc., 2016;

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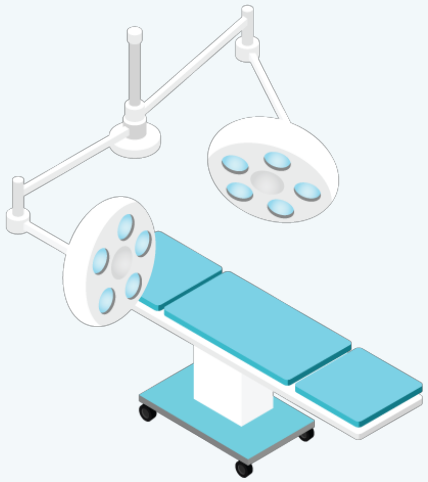
NON-DEGRADABLE IS SO 20TH CENTURY®

Morbidity Associated .

13 **out of 100** ureteral stents will be **forgotten**

10 of thee 13 will became **encrusted**, resulting in increased **risk of infection**, **obstruction** and retention



Requiring an average of
2 SURGICAL PROCEDURES
For stent removal

Source : Ather, Tech Urol, 2000; Bultitude Urology 2003; www.kidneystoners.org

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NON-DEGRADABLE IS SO 20TH CENTURY®

Biodegradable medical devices

- First product is a **biodegradable Ureteral stent**
- **60%** reduction of **€1000** actual treatment cost
- **10M** avoided surgeries

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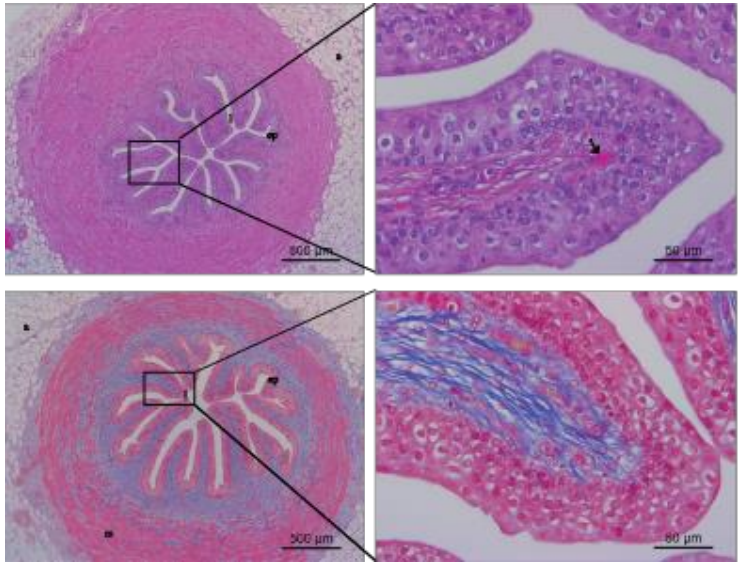
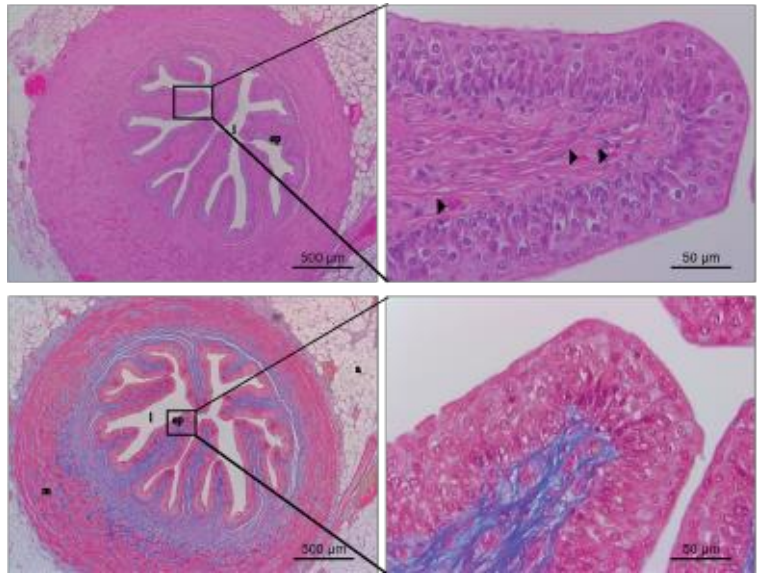
NON-DEGRADABLE IS SO 20TH CENTURY®

In vivo clinical validation .

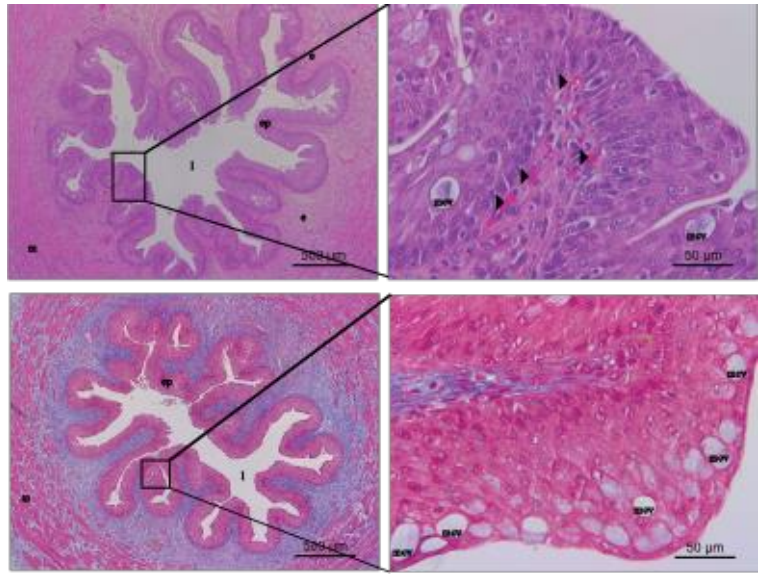
HydrUStent®



Control



Commercial (non-degradable)



HydrUStent – Epithelium remains intact, similar to the non-stented ureters;

Commercial – More aggressive to the ureter epithelium (Irregular surface, edema, epithelium destruction)

Source : Barros, World J Urol, 2018.

8. DEVELOPMENT TIMELINE .

8.1. BIODEGRADABLE URETERAL STENT

Urology.

Project Management - HydrUStent

2019 | 2020 | 2021 | 2022 | 2023 | 2024

Preliminary studies

Production Development

Mold development;
- Assembly trial;
- Pre-clinical studies.

Clinical evaluation and certification process

- Human clinical trials;
- CER;
- Identification of standards and GSPR;
- Risk management;
- DDF preparation.

CE

Commercialization

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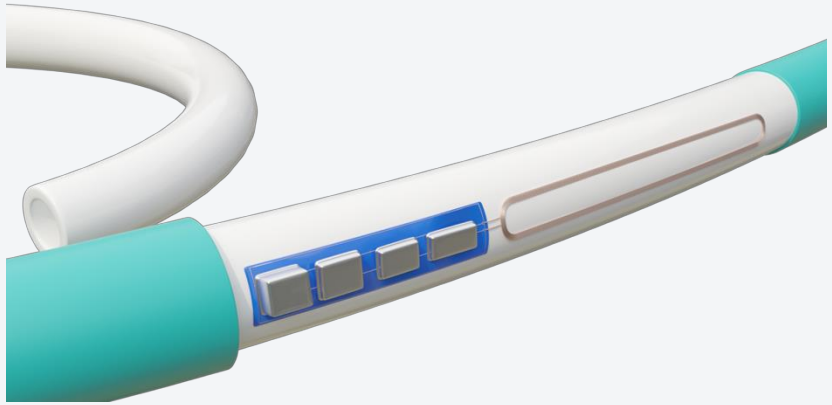
Hydrusensor™

Co-financed by

Urology.



Pressure sensor Urological devices, a wireless intrarenal and intravesical device for real-time urological pressure measurement and Urodynamics.

Patented Product

Market launch by 2023

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2. CLINICAL NEED .

Urology.

50% diagnostic failure

2.1 KEY POINTS

• Urodynamics is the current standard method for objectively diagnosing and differentiating lower urinary tract disorders, but it has major limitations, including adverse effects and complications, diagnostic failures and data reproducibility issues.

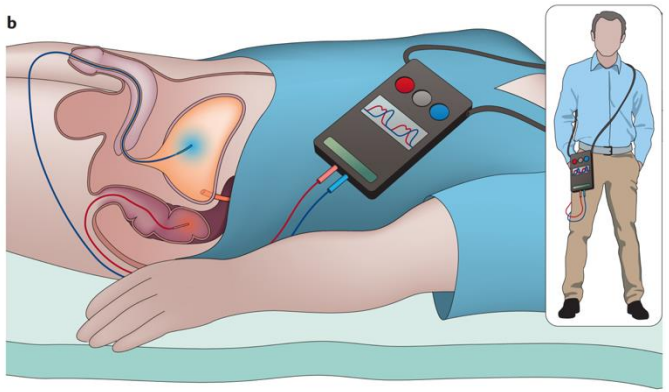
• Urodynamics is a snapshot examination in a clinical laboratory environment and involves catheterization, retrograde filling of the bladder (at faster-than-physiological rates) and observation of private bodily functions by clinical personnel.

• Ambulatory urodynamic monitoring (AUM) resolves some of the limitations of traditional urodynamic studies; nonetheless, AUM involves catheters and does not record bladder volumes other than residual urine and voided volume.

• Novel telemetric AUM (TAUM) systems using wireless, catheter-free, battery-powered devices for monitoring bladder pressure and volume during everyday activities in the privacy of a patient's home are under current development.

• To improve diagnostic accuracy and patient comfort, TAUM devices are innovating in the areas of remote monitoring, rechargeable energy sources, device deployment, retrieval and materials engineering.

Urodynamics test



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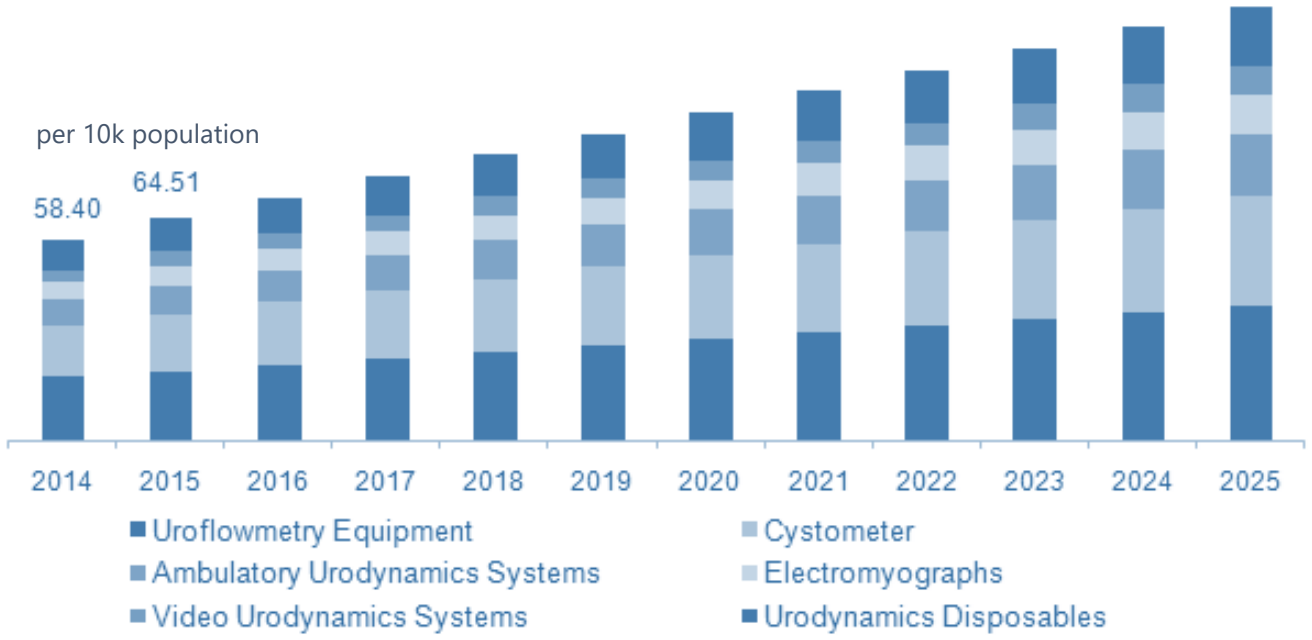
Urology.

€ 250 Million (50% disposable market)
Global Urodynamics Market .

CAGR of 6.32% from until 2022



- Number of cases per year: **3.8 – 6.2 tests per 1000 people**;
- Total cost for the testing of a patient with **Medicare coverage: ranges from € 350 to € 375**.
- Cost of the minimum urodynamic testing paid for by **private insurance ranged from € 600 to €1,000.**
- Initial investment in the **urodynamic equipment : € 15,000**.

- Urodynamic procedures in Germany (in 2020): > 95k
- Urodynamic procedures in Austria (in 2020): > 8k

Urodynamic Equipment And Consumables Market Size, Share & Trends Analysis Report By Type (Uroflowmetry Equipment, Cystometer, Ambulatory Systems, Electromyographs, Video Urodynamic Systems), And Segment Forecasts, 2018 – 2025, Report ID: GVR-1-68038-493-2

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8. DEVELOPMENT TIMELINE .

8.1. URODYNAMICS PLATFORM

Urology.

Project Management - HydrUSensor

2019 | 2020 | 2021 | 2022 | 2023 | 2024

Preliminary studies

- Technical specifications;
- Selection and characterization of technologies.

Development

- User interface optimization;
- SW development;
- Assembly trial;
- Pre-clinical studies.

Clinical evaluation and certification process

- Human clinical trials;
- CER;
- Identification of standards and GSPR;
- Risk management;
- DDF preparation.

Commercialization

CE

Capital need for manufacturing and validation

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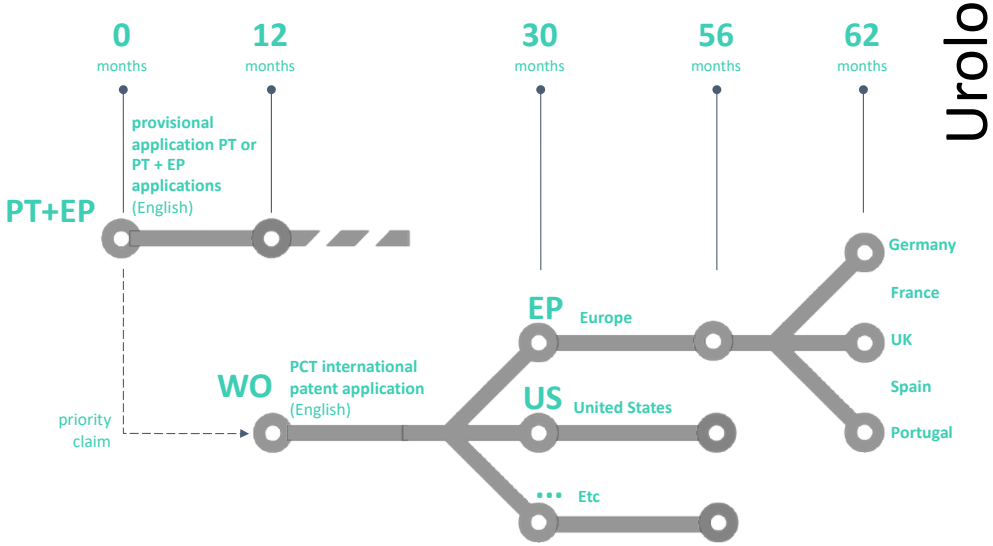
10. INTELLECTUAL PROPERTY .

- A Family of patents were filled in order to protect HydrUSensor technology for Urology and Gastroenterology applications as well the assembly of electronic components;
- A PT+EP strategy was taken with the objective to proceed for a WO PCT international patent application;
- A new application related to urodynamic platform is advise linked with other applications;
- Hydrumedical works with an International Patent office, Patentree, one of Europe's top 160 firms according to Financial Times and Statista´s special report on Leading European Patent Law Firms (2020).

International Route - PCT + EP/US/...

Assuming 5 years to reach grant, average times;



Urology.

Patent applications submitted by Hydrumedical and strategy for the Urodynamic platform protection

HydrUSensor assembly	PPP (20201000025910)	SENSOR FOR IMPLANTABLE STENT OR CATHETER AND MANUFACTURE METHOD THEREOF
HydrUSensor (Urology)	EP20168857 (priority)	IMPLANTABLE URETERAL STENT AND MANUFACTURE METHOD THEREOF
HydrUSensor (Gastroenterology)	PPP (20201000018098)	IMPLANTABLE BILIARY OR PANCREATIC STENT AND MANUFACTURE METHOD THEREOF
HydrUFlow	EP P734.5	DEVICE AND METHOD FOR MEASURING URINE FLOW
Urodynamic platform	EP Application Date: 2021	

Date	Urology	Gastroenterology	Sensor Assembly
Nov.2019	PT		
Mar.2020	EP	PT	PT
Nov.2020	PCT	-	-
Mar.2021	-	PCT	PCT
...			

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HYDRUMEDICAL

Our Infection Control Product Line effectively inactivates encapsulated virus (including Sars-Cov-2) .

COVID -19
CORONAVIRUS

Infection Control Line.

References

	Packaging	Top	Reference	Items per box
HYDRU® SURFACES	5 L	Cap	DHYDSF5000	N/A
	1 L	Trigger	DHYDSF1000	21
	1 L (refill)	Cap	DHYDSF1000R	21
	500mL	Trigger	DHYDSF500	41
	500mL (refill)	Cap	DHYDSF500R	41
HYDRU® HANDS	500mL	Dispenser	DHYDH500	41
	500mL (refill)	Cap	DHYDH500R	41
	75 ml	Spray	DHYDH0075	60
	50 ml	Foamer	DHYDH0050	R
HYDRU® Desinfectant	5 L	Cap	DHYD5000	N/A
	200mL	Flip top	DHYD0200	20
HYDRU® Tissues	40 tissues	--	DHYDT0040	R

R - upon request

Delivery Time	From the date the order is placed
≤ 10 pallets	7 to 14 days
> 10 pallets	Confirmed at the order placement

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Infection Control Line.

"No allergic or irritating reaction in all patients tested with HYDRU®HANDS"

Inês Moreira Lobo, MD

Dermatology Service Coordinator

CUF Porto Hospital

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INTERNATIONAL CERTIFICATIONS .

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

APCER has issued an IQNet recognized certificate that

the organization

HYDRUSTENT, S.A.

AvePark - Parque de Ciência e Tecnologia (Sala 213)
Zona Industrial da Gandra
4805-017 BARCO | GUIMARÃES - PORTUGAL

has implemented and maintains a

Quality Management System

for the following scope:
Research, design, development and innovation of medical devices

which fulfils the requirements of the following standard

ISO 9001:2015

Issued on: 2019-10-28
Expires on: 2022-10-27

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: PT- 2019/CEP.5679

Alex Stoichitoiu, President of IQNet — José Leitão, APCER CEO

IQNet Partners*:
AENOR Spain AFNOR Certification France APCER Portugal CCC Cyprus CISQ Italy
CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

Quality Management System

ISO 9001: 2015

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

APCER has issued an IQNet recognized certificate that

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HYDRUSTENT, S.A.

AvePark - Parque de Ciência e Tecnologia (Sala213)
Zona Industrial da Gandra
4805-017 BARCO | GUIMARÃES - PORTUGAL

has implemented and maintains a

Medical devices - Quality management systems - Requirements for regulatory purposes

for the following scope:
Research, design and development of medical devices

which fulfils the requirements of the following standard

ISO 13485:2016

Issued on: 2019-10-28
Expires on: 2022-10-27

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Registration Number: PT- 2019/SGMD.0037

Alex Stoichitoiu, President of IQNet — José Leitão, APCER CEO

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FCAV Brazil FONDONORMA Venezuela ICONTEC Colombia Inspecta Sertifiointi Oy Finland INTECO Costa Rica
IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia
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Medical Device Management System

ISO 13485:2016

apcer

Certificado
Certificate

NÚMERO 2019/IDI.0125
Number

O Sistema de Gestão da Investigação, Desenvolvimento e Inovação da
The Research, Development and Innovation Management System of

HYDRUSTENT, S.A.
AvePark - Parque de Ciência e Tecnologia (Sala 213)
Zona Industrial da Gandra
4805-017 BARCO | GUIMARÃES
PORTUGAL

implementado na investigação, design, desenvolvimento e inovação de dispositivos médicos, cumpre os requisitos da norma
implemented in the research, design, development and innovation of medical devices, meets the requirements of the standard

NP 4457:2007

IQNet — IPAC

José Leitão
CEO

Emitido em 2019-10-28
Date of issue
Válido até 2022-10-27
Valid until

APCER – Associação Portuguesa de Certificação
d'Porto Bessa Leite Complex | Rua António Bessa Leite, 1430 - 1º Esq.
4150-074 Porto

Innovation Management System

NP 4457

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Hydrumedical new building with production line.

Facilities (1600 m²)

- Laboratories
- 120 m² Clean room for production
- 12 m² Clean room quality validation
- Warehouse
- Offices

Estimation 2022

PARQUE CIÊNCIA TECNOLOGIA

https://www.avepark.pt/

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