PUSEN®

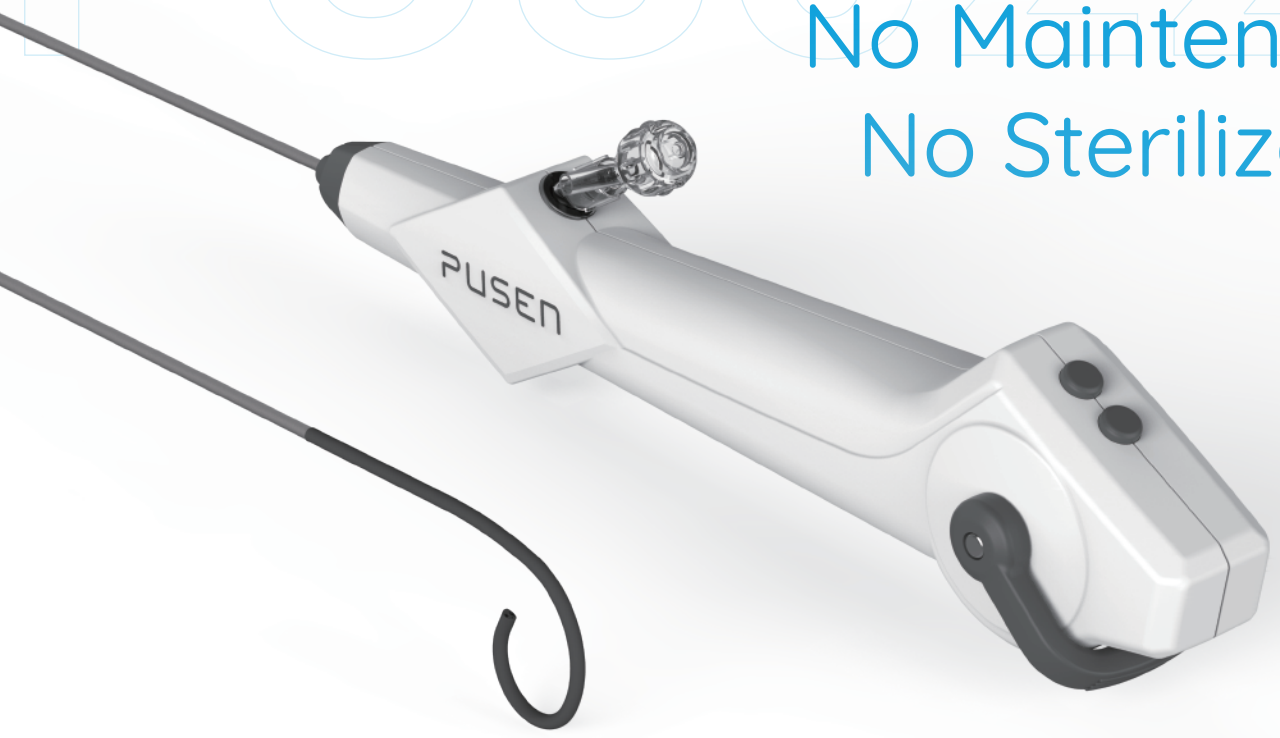
Digitally signed by Bunic Gheorghe
Date: 2023.08.27 17:40:07 EEST
Reason: MoldSign Signature
Location: Moldova

Single-use Digital Flexible Ureteroscope

PU3022A
PU3022

PU3022A

No Cross Infection
No Maintenance
No Sterilization



Specification

Optical System	
Field of View	90°
Direction of View	0°
Depth of Field	3-50 mm
Image Resolution	5 Lp/mm
Illumination	Optical Fiber
Insertion Portion	
Controllable Portion	≥270° Up | ≥270° Down
Diameter of Insertion Portion	9.2 Fr
Working Length	650 mm
Channel	
Working Channel	3.6 Fr
Irrigation	30 mL/min

Greater Tip Range of Motion

Passive Bending

Two-way Deflection

1:1 Torque Ratio

PUSEN®

Zhuhai Pusen Medical Technology Co., Ltd.
5/F Building 1, No.33, Keji San Road
High-tech Zone, Tangjiawan Town,
519085 Zhuhai, Guangdong, People's Republic of China
www.pusenmedical.com

For medical professionals only

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Rev.202104

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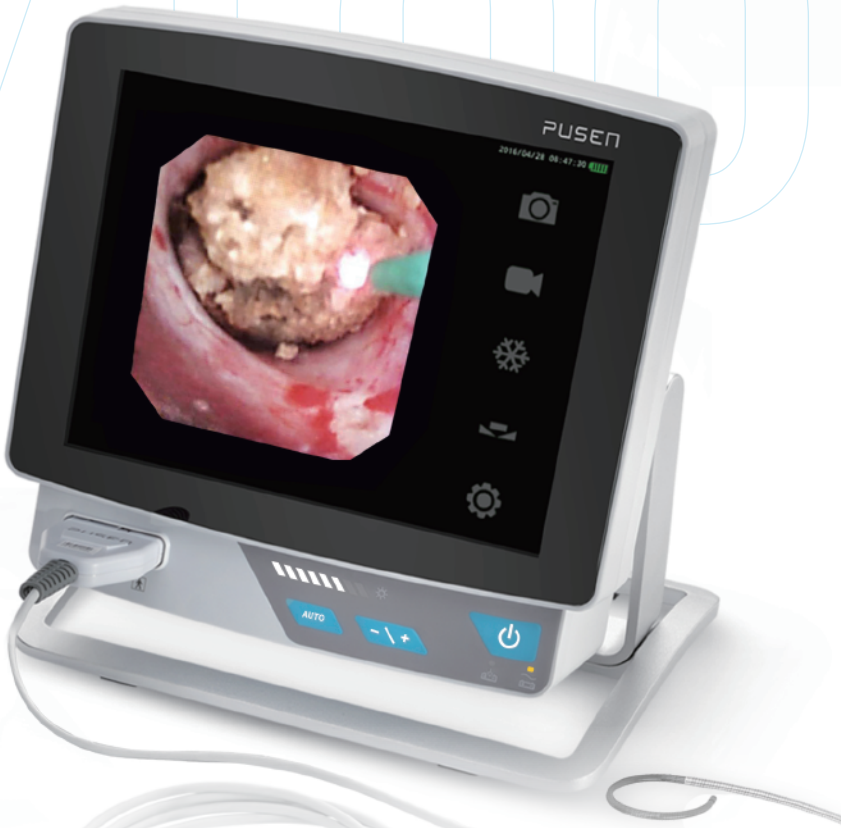
Image Processor

UTV100

UTV100

Touchscreen
Portable
Plug-and-Play



Touchscreen

8GB

Mass Storage

External Display

Specification

UTV100 Image Processor	
Screen Resolution	1024 * 768
Display	12.1"
Storage	8G
Video Interface	RCA, HDMI
Recording	Over 500 photos Over 30 minutes videos

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 092464 0013 Rev. 00

Manufacturer:

Zhuhai Pusen Medical Technology Co, Ltd.
5/F, Building 1, No 33, Keji San Road
High-tech Zone, Tangjiawan Town
519085 Zhuhai, Guangdong
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Zhuhai Pusen Medical Technology Co., Ltd.
4/F, Building 4, No.20, Jinfengxi Road, High-tech Zone,
Tangjiawan, 519080 Zhuhai, PEOPLE'S REPUBLIC OF CHINA

Zhuhai Pusen Medical Technology Co, Ltd.
5/F, Building 1, No 33, Keji San Road, High-tech Zone,
Tangjiawan Town, 519085 Zhuhai, Guangdong, PEOPLE'S REPUBLIC OF CHINA

Zhuhai Pusen Medical Technology Co., Ltd.
Changshapu, Cuiheng Village, Nanlang, 528454 Zhongshan,
Guangdong, PEOPLE'S REPUBLIC OF CHINA

Product Category(ies): Medical Video Endoscope

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 devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: SH1994301

Valid from: 2019-10-29
Valid until: 2024-05-26

Date, 2019-10-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

A4 / 07.17

Declaration of Conformity

Manufacturer	Zhuhai Pusen Medical Technology Co., Ltd.
Address	5/F, Building 1, No. 33, Ke Ji San Road, High-tech zone, Tang Jia Wan Town, Zhuhai, Guangdong, China.
European Representative	Shanghai International Holding Corp .GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
ProductName	Medical Video Endoscope Image Processor
UMDNS Code	18034
Model	UTV100, PV210

Classification: Class I, rule 12 of Annex IX of the MDD 93/42/EEC

Conformity Assessment Route: Annex VII of the MDD 93/42/EEC

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the EC Council Directives 93/42/EEC and applicable harmonized Standards. We are exclusively responsible for this document. All supporting documentations are retained under the premises of the manufacturer.

Name Huang Honghui

Position General Manager

Signature: Huang Honghui

Date: 2017-12-25

EU Declaration of Conformity

Manufacturer: Zhuhai Pusen Medical Technology Co., Ltd.

Address: 5/F, Building 1, No 33, Keji San Road, High-tech Zone, Tangjiawan Town, 519085 Zhuhai, Guangdong, China.

SRN: CN-MF-000009220.

European Representative: Umedwings Netherlands B.V.

Address: Treubstraat 1, 2288EG, Rijswijk, the Netherlands.

SRN: NL-AR-000000444.

Medical devices:

#	Product Name	Model	UMDNS Code	Basic UDI-DI (GMN)	Classification
1)	HD Medical Video Endoscope Image Processor	PV300	18034	697117628EDN	Class I - per Rule 13 of Annex VIII of the Regulation (EU) No. 2017/745 (MDR).
2)	Medical Video Endoscope Image Processor	PV220			
3)	Medical Video Endoscope Image Processor	PV210			
4)	Medical Video Endoscope Image Processor	UTV100			

General applicable Regulations: Regulation (EU) No. 2017/745 (the MDR) as well as its amendment and Corrigendum.

Conformity Assessment Route: this EU declaration of conformity is issued after drawing up the technical documentation set out in Annexes II and III of Regulation (EU) No. 2017/745.

Standards and CS applied: Please refer to below "Annex - Standards and CS applied".

Manufacturer Statement: We herewith declare that the above mentioned medical devices are in conformity with the Regulation (EU) No. 2017/745 (the "MDR"), applicable CS and harmonized Standards. We are exclusively responsible for this document. All supporting documentations are retained under the premises of the manufacturer.

On behalf of Zhuhai Pusen Medical Technology Co., Ltd.,

(Signature) Huang Honghui

General manager: Honghui Huang.

Place, Date of issue: Zhuhai, Guangdong, PRC, 2023-03-06.

Valid until: 2024-03-05.

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Annex - Standards and CS applied

#	Reference No. of standard/CS	Title of standard/CS
1)	EN 60601-1:2006+A1:2013+A12:2014+A1:2021	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2)	EN 60601-1-2:2015+A1:2021	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3)	EN 60601-2-18:2015	Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
4)	ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
5)	ISO 14971:2019	Medical devices — Application of risk management to medical devices
6)	EN 60601-1-6:2010+A1:2015+A2:2021	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
7)	EN 62366-1:2015+A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
8)	ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
9)	ISO 780:2015	Packaging — Distribution packaging — Graphical symbols for handling and storage of packages
10)	IEC 62304:2006+AMD1 2015	Medical device software - Software life cycle processes

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