

COMPLIANCE CERTIFICATE

We certify that the Technical Documentation of the below mentioned products (Medical Devices Directive 2007/47/EC) According to the Council Directive 93/42/EEC as amended (2007/47/EC).

ARK MEDITECH SYSTEMS

21/B, MANINAGAR CO-OPERATIVE HOUSING
SOCIETY, OPP. GOPAL TOWER, MANINAGAR,
AHMEDABAD - 380008, GUJARAT (INDIA)

has been assessed and conforms to:



Applicable to products : As Pre Annexure 1st & 2nd

Complies with the applicable requirements of the Directive 93/42/EEC as amended (2007/47/EC) Referring to the intended use, the Certification body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to the above mentioned Directive and appropriate Harmonized European Standards.

This Certificate is issued under the following conditions:-

- ❖ The Manufacturer's Technical Documentation, as required for MDD 2007/47/EC, has been reviewed and found to comply with the requirements in Annex VII, Section 3.
- ❖ It applies only to the above mentioned Medical Devices.
- ❖ The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this certificate.
- ❖ Any significant changes in the design or process use to manufacture the product or revision to the directive or standards referred above may require special audit.

Certificate Number : CE-15-1112

Original Certification Date : 10/07/2015 1st Surveillance Due on : 08/07/2016

Certificate Expiration Date : 09/07/2018 2nd Surveillance Due on: 06/07/2017



Deutsche Accreditation Board

Otto-Hahn-Ring 6, D-81739 Muenchen, Germany
E-mail: markglobal2014@gmail.com Website: www.dabaccreditation.com

Certification Manager

The validity of this certificate is contingent upon the condition that the client has understood & shall abide by contract agreement, certification agreement for certification services and logo rules as given on our website www.dabaccreditation.com. The client is request to check the above certificate details at our above mentioned website and also on www.dabaccreditation.com, under the heading of Register & Sub heading of certified organization by entering their certificate number and inform us in case of any discrepancy at our above email id

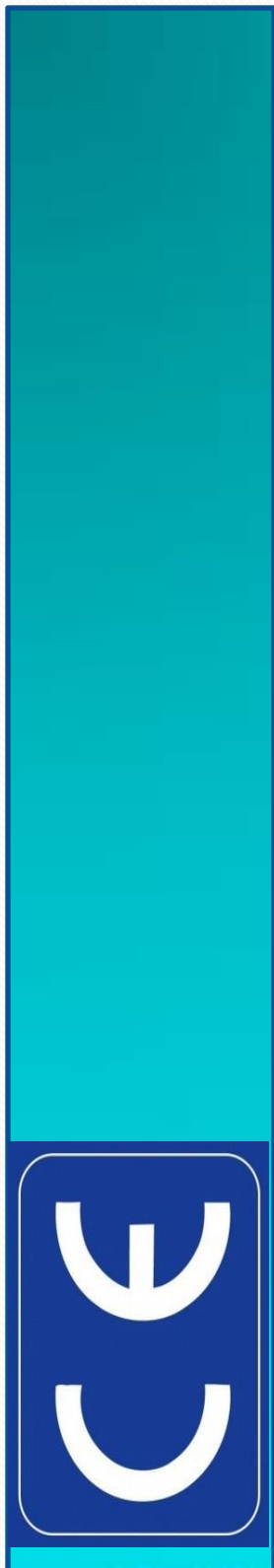
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Product List: -

Annexure 1st

- **INTRA CORPOREAL PNEUMATIC LITHOTRIPSY SYSTEM “LITHO-MED” DIGITAL**
- **UROFLOWMETRY UROFLOW SYSTEM**
- **UROUMP**
- **NEW DEVICE FOR IRRIGATION OF FLUID.**
- **CYSTOSCOPY ACCESSORIES**
- **MAUERMAYER STONE PUNCH WITH OPTCHURATOR**
- **SINGLE CHANNEL BRIDGE**
- **DOUBLE CHANNEL BRIDGE**
- **CYSTOSCOPIC SHEATH WITH OBTURATOR**
- **LITHO BRIDGE**
- **STONE CRUSHER**
- **OPTICAL BIOPSY FORCEP WITH OBTURATOR**
- **FLEXIBLE STENT REMOVING FORCEPS WITH TEFLON SLEAVE**
- **FLEXIBLE BIOPSY FORCEPS WITH TEFLON SLEAVE**
- **RESECTOSCOPE SET**
- **V.I.U SHEATH 21FR WITH OBTURATOR WITH HALF MOON SHEATH**
- **TURP VISUAL OBTURATOR**
- **OTIS URETHRETOMY**
- **UROLOGY FORCEPS**
- **U.R.S ALLIGATOR FORCEPS**
- **U.R.S TRIPRONGE FORCEPS**
- **U. HANDLE U.R.S BIPRONGE FORCEPS**
- **U HANDLE U.R.S..CLOT FORCEPS**



ARK MEDITECH SYSTEMS

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Product List: -

Annexure 2nd

- PCNL PEANUT FORCEPS
- P.C.N.L ALIGATOR FORCEPS
- P.C.N.L CLOT FORCEPS
- U HANDLE P.C.N.L.CLOT FORCEPS
- U. HANDLE PCNL TRIPRONGE FORCEPS
- U. HANDLE P.C.N.L. BIPRONGE FORCEPS
- PCNL METAL DIALATOR SET
- UROLOGY DISPOSABLES
- DOUBLE- J STENT (WHITE)
- DORMIA BASKET (HELICAL & SEGURA)
- TURP LOOP SINGLE STEM REGULAR
- TURP LOOP DOUBLE STEM

