



Procedo
INTERNATIONAL CERTIFICATION



CERTIFICATE

This is to certify that the Quality management system for medical devices of company

ASTER MEDISPRO PVT. LTD.

S. P. 181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate,
Jigani Industrial Area, Jigani, Bangalore - 560 105, Karnataka, India

Company's Logo



has been found in compliance with requirements of the standard

EN ISO 13485: 2016

for the following scope:

**Design, Manufacture and Sales of Medical Devices for Urology, Gastroenterology, In-Vitro Fertilization, Oncology, Intervention Radiology and Brachytherapy Accessories
Catheter;**

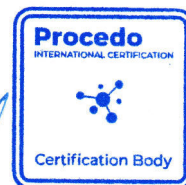
Manufacture and sales of electrodes used for Ablation purpose;

Certificate no. : QMS-13-015-2021

Date of issue: 01/10/2021


Initial certificate issue: 01/10/2021

On condition that the organisation will maintain an effective quality management system for medical devices, this certificate remains valid to 30/09/2024.



Ing. Ľubica Škrovanová
Head of Certification body



 ASTER <i>...More Respected & Respected</i>	ASTER MEDISPRO PVT.LTD	Ref No.: DAD07F(18)
	EC DECLARATION OF CONFORMITY	Revision No.: 06
		Revision Date: 03-12-2020

PWe:

Company Name	ASTER MEDISPRO PRIVATE LIMITED
Company Address	S.P 181, 10 TH Main, 1 ST Stage, Dr. B.R Ambedkar Industrial Estate, Jigani Industrial Area, Jigani, Bangalore- 560105. Karnataka (INDIA)

Declare under our sole responsibility that the:

Product Name(s)	MEDICAL DEVICES FOR UROLOGY	Model/Type Ref(s)	Listed in Annexure 1
Classification and Classification Rule	Listed in Annexure 1		
GMDN Code	Listed in Annexure 1		
Product Details	Listed in Annexure 2		

Conformity Assessment : Annex II, Excluding Section 4 of Council Directive 93/42/EEC and its Revised Version.

We declare that the above-mentioned products meet the provisions of the Council Directive 93/42/EEC, all prior amendments and as transposed into national laws. All supporting documentation is retained under the premises of the manufacturer.

Standards Applied:


EN ISO 13485: 2016, EN ISO 14971:2012 , EN ISO 11737 1:2006/AC:2009,
 EN ISO 11737-2:2009, EN ISO 11140-1:2009, EN 556-1:2001/AC:2006,
 EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993-1:2009/AC:2010,
 EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-12:2012,
 EN ISO 11135-1:2007, EN ISO 11138-2:2009, EN 1422:1997+A1:2009

ISO 11140-1:2014, ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5:2009,
 ISO 10993-6:2016, ISO 10993-7:2008/AMD 1:2019, ISO 10993-10:2010,
 ISO 10993-11:2017 ISO 14644-1:2015, ISO 14644-2:2015, ISO 14644-9:2012
 ISO 11138-1:2017, BS EN 13868:2002, IEC 62366-1:2015,
 ASTM F1980-07:2011, ASTM F88-15, ASTM F1140-13

Proposed Notified Body	MTIC Intercer S.r.l Via G.Leopardi, 14 20123 – Milano (MI) Italy Notified Body Number: 0068
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EC Certificate	Certificate(s) Number: Urology Catheters - 0068/QCO-DM/244-2020 Urology Dilators - 0068/QCO-DM/245-2020 Urology Retrievers - 0068/QCO-DM/247-2020 Issued On: 03/12/2020 Valid up to: 27/05/2024
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 ASTER <i>Always Referred To Radio</i>	ASTER MEDISPRO PVT.LTD	Ref No.: DAD07F(18)
	EC DECLARATION OF CONFORMITY	Revision No.: 06
		Revision Date: 03-12-2020

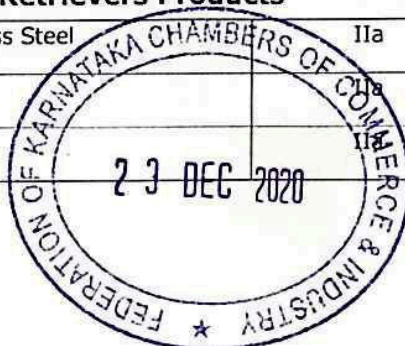
European Representative	M/sCMC Medical Devices& Drugs S.L Located in C/HoracioLengo Nº 18, CP 29006, Málaga, Spain E-mail : mmateos@cmcmedicaldevices.com Website : www.cmcmedicaldevices.com Tel: +34951214054 Fax: +34952330100
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 ASTER <i>Where Research Is Routine</i>	ASTER MEDISPRO PVT.LTD	Ref No.: DAD07F(18)
	EC DECLARATION OF CONFORMITY	Revision No.: 06
		Revision Date: 03-12-2020

**LIST OF PRODUCTS WITH MODELS, CLASSIFICATION RULE AND GMDN CODE
LISTED IN ANNEXURE-1**

GMDN CODE	PRODUCT TYPE AND DESCRIPTION	CLASSIFICATION	CLASSIFICATION RULE
Urology Catheters			
10761	Ureteral Catheter with variant Close Tip,(CT),Open Tip (OT),Angle TIP (AT), Cone Tip (CT),Whistle Tip (WT)	IIa	5
10735	Malecot Catheter	IIa	7
10735	PCN Catheter	IIa	7
10735	PCN Catheter with Needle	IIa	7
10735	Suprapubic Catheter	IIa	7
10765	CIC Catheter	IIa	5
10764	Tiemann Catheter	IIa	5
10735	Re-Entry Malecot Catheter	IIa	7
10735	PCN Catheter Set	IIa	7
10735	Malecot Catheter Set	IIa	7
10761	Urodynamic Catheter	IIa	5
14235	Amplatz Sheath	IIa	7
11254	Ureteral Access Sheath	IIa	7
11265	Ureteral Balloon Dilation Catheter	IIa	5
Urology Dilators			
16468	Ureteral Dilator	IIa	5
15215	Fascial Dilator	IIa	7
16468	Nottingham Dilator	IIa	5
11254	Meatal Dilator	IIa	5
11254	Amplatz Renal Dilator Set	IIa	7
11265	Urethral Filliform Dilator	IIa	5
11254	Fascial Dilator Set	IIa	7
16468	Urethral Dilator	IIa	5
16468	Ureteral Dilator Set	IIa	5
11254	Renal Dilator	IIa	5
Urology Retrievers Products			
17574	Stone Basket - Stainless Steel	IIa	5
17574	Stone Basket - Nitinol	IIa	5
17574	Stone Grasper	IIa	5



 ASTER <i>...Where Revered Is Routine</i>	ASTER MEDISPRO PVT.LTD	Ref No.: DAD07F(18)
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15809	Bladder Evacuator	IIa	2
14301	Track Finder Bulb Irrigator	IIa	2
15256	Toomey Tip Syringe	IIa	2
16040	Stent Remover	IIa	5
14301	TUR Set	IIa	5





ASTER MEDISPRO PVT. LTD.
EC DECLARATION OF CONFORMITY

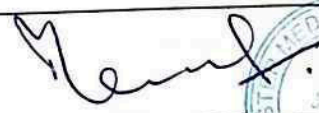
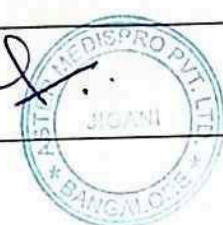
Ref No.: DAD07F(18)
Revision No.: 06
Revision Date: 03-12-2020

PRODUCT DETAILS


LISTED IN ANNEXURE-2

List of products covered in the Declaration (Ref.....)

REF	Description	Quantity	Lot Number

Name	Manikandan Thachat	 
Designation	Director-Marketing	
Place & Date of Issue	22-12-2020	

ATTESTED
Federation of Karnataka Chambers
of Commerce and Industry


SABU SUPRIYAN.P.
Secretary



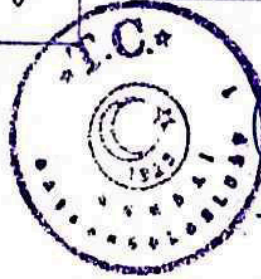
BL

T.C.
Mumbai Başkonsolosluğu
Maker Chambers IV, 222, Jamnalal Bajaj Road,
No: 101, 10. Kat, Nariman Point, Mumbai - 400021
HINDISTAN

Asağıdaki

Yukarıdaki imza ve mührün,
mente şamil olmamak üzere
Hindistan Dışişleri Bakanlığı'na
ait olduğu onaylanır.

Tarife bendi: 5/111/3a
Miktar: 1430/-
Makbuz No.: 27945400
Tarih: 07-01-2021



Ahmet DENK
Konsolos

95525

28 DEC 2020

सं०
No.
दिनांक
Date
अभिलेख संख्या में तत्काल संपादन एवं प्रमाण/संक्षिप्त के
हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asstt. Secretary/Dy.
Secretary/Secretary of Chamber of
Commerce Attestation.
विदेश मंत्रालय इस दस्तावेज के किसी भी विषय वस्तु
की जिम्मेदारी नहीं लेता।
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(सुनील चनाप)
(SUNIL CHANAP)
अनुभाग अधिकारी (ओ.आई.)
Section Officer (OI)
सी. पी. वा. प्रभाग / C.P.V. Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi



MTIC
INTERCERT

C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/244-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

Aster Medispro Private Limited

S.P.181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate, Jigani
Industrial Area, Jigani, Bangalore – 560 105, Karnataka (INDIA)

DEVICE/S:

Urology Catheters

MODEL/S:

✓ Ureteral Catheter with variants:

Close Tip (CT), Open Tip (OT), Angle Tip (AT), Cone Tip (CT), Whistle Tip (WT)

✓ Malecot Catheter

✓ PCN Catheter

✓ PCN Catheter With Needle

✓ Suprapubic Catheter

✓ CIC Catheter

✓ Tiemann Catheter

Re-Entry Malecot Catheter

✓ PCN Catheter Set

✓ Malecot Catheter Set

Urodynamic Catheter

✓ Amplatz Sheath

✓ Ureteral Access Sheath



FIRST ISSUE: 03/12/2020

CURRENT ISSUE: 03/12/2020

REVISION Nr.: 00

EXPIRING DATE: 27/05/2024

ATTESTED

Federation of Karnataka Chambers
of Commerce and Industry

SABU SUPRIYAN.P.

Secretary

Dipl.-Ing. Feridoon Sergizaree

MTIC INTERCERT Certification Body

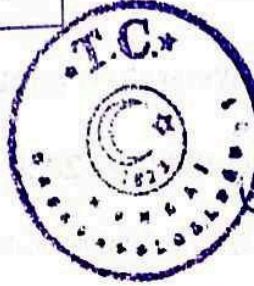
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Mumbai Başkonsolosluğu
Maker Chambers IV, 222, Jamnalal Bajaj Road,
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HINDİSTAN

Asağıdaki

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Hindistan Dışişleri Bakanlığına
ait olduğu onaylanır.

Tarife bendi: 5/III/3a
Miktar: 1430/-
Makbuz No.: 27945400
Tarih: 07.01.2021



Ahmet DENK
Konsolos

95526

28 DEC 2020

सं०
No.

दिनांक
Date

तलिय मंजूर मे सहायक सचिव आ सचिव/तलिय के
दस्तावेज तलिय मंजूर मे ।
The Signature of Asstt. Secretary/Dy.
Secretary/Secretary of Chamber of
Commerce Attested.
विदेश मंत्रालय इन दस्तावेज के तलिय मे विषय वस्तु
की जिम्मेदारी नहीं लेता ।
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(SUNIL CHANAP)
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi.



C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/246-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MTIC Intercert hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. MTIC Intercert certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER:

Aster Medispro Private Limited

S.P.181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate, Jigani Industrial Area, Jigani, Bangalore – 560 105, Karnataka (INDIA)

DEVICE/S:

Urology Retrievers

MODEL/S:

- | | |
|----------------------------------|--------------------------|
| ✓ Stone Basket – Stainless Steel | ✓ Stone Basket - Nitinol |
| ✓ Stone Grasper | ✓ Bladder Evacuator |
| ✓ Track Finder Bulb Irrigator | ✓ Toomey Tip Syringe |
| ✓ Stent Remover | ✓ TUR Set |

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EXPIRING DATE: 27/05/2024

ATTESTED
Federation of Karnataka Chambers
of Commerce and Industry

SABU SUPRIYAN.P.
Secretary



Ing. Feridoon Sengizarea
MTIC INTERCERT Certification Body

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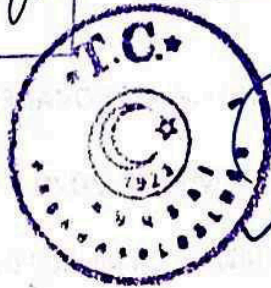
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T.C.
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Maker Chambers IV, 222, Jamnalal Bajaj Road,
No: 101, 10. Kat, Nariman Point, Mumbai - 400021
HİNDİSTAN

Asagidaki

Yukarıdaki imza ve mührün,
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Hindistan Dışişleri Bakanlığına
ait olduğu onaylanır.

Tarife bendi: 5111/3a
Miktar: 1430/-
Makbuz No.: 27945400
Tarih: 07.01.2021



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Konsolos

95527

28 DEC 2020

सं०
No.
दिनांक
Date
आपका पत्र मे सत्यक सचिव का मंत्रि/सचिव के
हस्ताक्षर तालिका लिए जाते है।
The Signature of Asstt. Secretary/Dy.
Secretary/Secretary of Chamber of
Commerce Attached.
विदेश मंत्रालय इन दस्तावेज के लिए भी विषय वस्तु
के लिए जिम्मेदार नहीं है।
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(SUNIL CHANAP)
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विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi





C E R T I F I C A T E

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/245-2020

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

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MANUFACTURER:

Aster Medispro Private Limited

S.P.181, 10th Main Road, 1st Stage, Dr. B. R. Ambedkar Industrial Estate, Jigani Industrial Area, Jigani, Bangalore – 560 105, Karnataka (INDIA)

DEVICE/S:

Urology Dilators

MODEL/S:

- | | | |
|--------------------------------------|-----------------------|-----------------------------|
| ✓ Ureteral Balloon Dilation Catheter | ✓ Ureteral Dilator | ✓ Fascial Dilator |
| ✓ Nottingham Dilator | ✓ Meatal Dilator | ✓ Amplatz Renal Dilator Set |
| ✓ Urethral Filliform Dilator | ✓ Fascial Dilator Set | ✓ Urethral Dilator |
| ✓ Ureteral Dilator set | ✓ Renal Dilator | |



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Secretary INTERCERT S.r.l. - Via Moscova, 11 - 20017 RHO (MI) - ITALY
www.mticert.org

Dipl.-Ing. Feridoon Sengizaree
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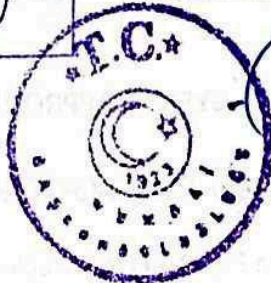
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HINDISTAN

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ait olduğu onaylanır.

Tarife bendi: 5/III/3a
Miktar: 1430/-
Makbuz No.: 27945400
Tarih: 07.01.2021



Ahmet DENK
Konsolos

95528

28 DEC 2020

सं. No. दिनांक Date
अधिकृत संज्ञा में प्राप्त तद्विषय का सचिव/सचिव के
हस्ताक्षर सत्यापित किए जाते हैं।
The Signature of Asst. Secretary/Dy.
Secretary/Secretary of Chamber of
Commerce Attested.
विदेश मंत्रालय का दस्तावेज के विषय में विषय वस्तु
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अनुभाग अधिकारी (ओ आई)
Section Officer (OI)
ओ पी सी प्रभाग/CPV Division
विदेश मंत्रालय, नई दिल्ली
Ministry of External Affairs, New Delhi

URETERAL ACCESS SHEATH



Product Code (Ürün Kodu)	Catheter Length (Kateter uzunluğu)	Catheter I.D (Kateter iç çapı)	Catheter O.D (Kateter Dış çapı)
UAS-9,5/11-35 CM	35 cm	9,5 fr	11,5 fr
UAS-9,5/11,5-40 CM	40 cm	9,5 fr	11,5 fr
UAS-9,5/11,5-45 CM	45 cm	9,5 fr	11,5 fr
UAS-9,5/11,5-50 CM	50 cm	9,5 fr	11,5 fr
UAS-9,5/11,5-55 CM	55 cm	9,5 fr	11,5 fr
UAS-10,5 /13.5-35 CM	35 cm	10,5 fr	13,5 fr
UAS-10,5 /13.5-40 CM	40 cm	10,5 fr	13,5 fr
UAS-10,5 /13.5-45 CM	45 cm	10,5 fr	13,5 fr
UAS-10,5 /13.5-50 CM	50 cm	10,5 fr	13,5 fr
UAS-10,5 /13.5-55 CM	55 cm	10,5 fr	13,5 fr
UAS-12/14-35 CM	35 cm	12 fr	14 fr
UAS-12/14-40 CM	40 cm	12 fr	14 fr
UAS-12/14-45 CM	45 cm	12 fr	14 fr
UAS-12/14-50 CM	50 cm	12 fr	14 fr
UAS-12/14-55 CM	55 cm	12 fr	14 fr