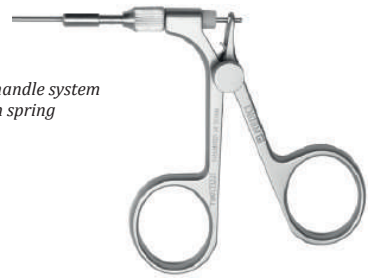
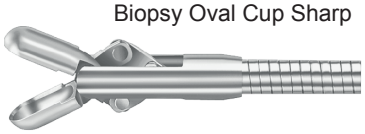
Cysto-UrethroscopeForceps,wl400mm



Fix handle system
With spring

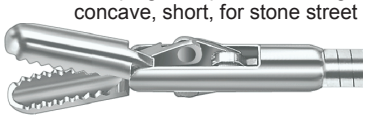
Flexible	Semi Rigid	Ø Ch	Ø mm
42004008	42004008S	2,5	0,8
42004010	42004010S	3,0	1,0
42004012	42004012S	3,5	1,2
42004014	42004014S	4,0	1,4
42004016	42004016S	5,0	1,6
42004021	42004021S	6,0	2,1
42004023	42004023S	7,0	2,3
42004030	42004030S	9,0	3,0

Biopsy Oval Cup Sharp



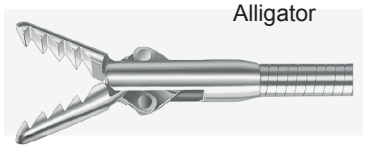
Flexible	Semi Rigid	Ø Ch	Ø mm
42074012	42074012S	3,5	1,2
42074016	42074016S	5,0	1,6
42074023	42074023S	7,0	2,3

Grasping forceps, interlocking teeth, concave, short, for stone street



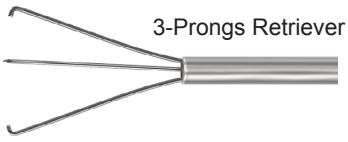
Flexible	Semi Rigid	Ø Ch	Ø mm
42044008	42044008S	2,5	0,8
42044010	42044010S	3,0	1,0
42044012	42044012S	3,5	1,2
42044014	42044014S	4,0	1,4
42044016	42044016S	5,0	1,6
42044023	42044023S	7,0	2,3
42044030	42044030S	9,0	3,0

Alligator



Flexible	Semi Rigid	Ø Ch	Ø mm
42094010	42094010S	3,0	1,0
42094016	42094016S	5,0	1,6
42094023	42094023S	7,0	2,3

3-Prongs Retriever



Endomed S.r.l.

ISO 13485
BUREAU VERITAS Certification

Dichiarazione di conformità n. 08/20
DECLARATION OF CONFORMITY

La Società ENDOMED S.R.L.S., con sede legale in Via Ugo La Malfa snc, 04020 Spigno Saturnia (LT), dichiara, sotto la propria totale responsabilità, che i dispositivi medici
We undersigned ENDOMED S.R.L.S., with registered office addressed in Via Ugo la Malfa snc – 04020 Spigno Saturnia (LT), declare under its own responsibility that the medical devices

Strumento per elettrochirurgia, classe di rischio IIb, in accordo alla regola 9
Strumento per Artroscopia, classe di rischio IIa, in accordo alla regola 7
Strumento per Cistouretroscopia, classe di rischio IIa, in accordo alla regola 7
Strumento per Nefroscopia, classe di rischio IIa, in accordo alla regola 7
Strumento per Resettoscopia, classe di rischio IIa, in accordo alla regola 7
Strumento per Uretrotomia, classe di rischio IIa, in accordo alla regola 7
Strumento per Isteroscopia, , classe di rischio IIa, in accordo alla regola 5
Instrument for electrosurgery*, risk class IIb, according to rule 9*
Arthroscopy instrument*, risk class IIa, according to rule 7*
Instrument for Cystourethroscopy*, risk class IIa, according to rule 7*
Nephroscopy instrument*, risk class IIa, according to rule 7*
Resectoscopy instrument*, risk class IIa, according to rule 7*
Urethrotomy instrument*, risk class IIa, according to rule 7*
Hysteroscopy instrument*, risk class IIa, according to rule 5*

dell'allegato IX della Direttiva 93/42/CEE e ss.mm.ii. (recepita in Italia con D.lgs. 24/02/97, n. 46, e ss.mm.ii.), così come modificata dalla Direttiva 2007/47/CE (recepita in Italia con Decreto Legislativo 25 gennaio 2010, n. 37),
of Annex IX of Directive 93/42 / EEC and subsequent amendments (transposed in Italy with Legislative Decree 24/02/97, n. 46, and subsequent amendments), as amended by Directive 2007/47 / CE (transposed in Italy with Legislative Decree 25 January 2010, n . 37) ,

- sono conformi ai requisiti essenziali ed alle disposizioni della Direttiva 93/42/CEE e ss.mm.ii. come da Fascicolo Tecnico n. FT 008 EM;
comply with essential requirements and dispositions of the Directive 93/42/EEC and further amendments, as the Technical File n. FT 008 EM retained by the Company;
- sono fabbricati in accordo al Sistema Qualità che soddisfa i requisiti di cui all'Allegato II del sopra citato decreto legislativo, come da Certificato n. IT280019 rilasciato in data 19/03/2018 da BUREAU VERITAS ITALIA S.p.a. Organismo - Notificato n. 1370, Viale Monza, n. 347 - 20126 MILANO.
are manufactured according to the Quality System that meets the requirements of Annex II of the mentioned legislative decree, as per Certificate no. IT280019 issued on 19/03/2018 by BUREAU VERITAS ITALIA S.p.a. Body - Notified n. 1370, Viale Monza, n. 347 - 20126 MILANO.

Formia (LT), 10/01/23

Il legale Rappresentante
Legal representative
(Michele Lionetti)

ENDOMED srls
Via Appia lato Napoli, 220
Presso Centro Ziggurat
04023 Formia (LT)
Part. IVA 02922120593

«ERICON» S.R.L.

BUREAU VERITAS
Certification

ENDOMED SRLS

Via Appia Lato Napoli, 220 - 04023 Formia (LT) – ITALY

Certified site:

Via Ugo la Malfa snc – 04020 Spigno Saturnia (LT) – ITALY

Bureau Veritas Italia S.p.A. certifies that the Full Quality Assurance System of the above organization has been audited and found to be in accordance with the requirements of

DIRECTIVE 93/42/EEC

(in accordance with Annex II - excluding paragraph 4)

In relation to the following products

Subcategory:	Active surgical devices
Generic group:	Electrosurgery, hysteroscopy, nephroscopy, arthroscopy, cystoscopy, resectoscopy and urethrotomy instruments
Model:	See Annex
Class:	See Annex

(may refer to the Annex of the certificate that lists all the products / models of devices subject to certification)

Reference BV practice: ZIG. N. **60526016**

Original cycle start date: **19 March 2018**

Expiry date of previous cycle: **na**

Certification / Recertification Audit date: **04 January 2018**

Certification / Recertification cycle start date: **19 March 2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **18 March 2023**

Certificate No. - Version: IT280019 - 3

Revision date: **20 July 2020**

ANDREA FILIPPI – Certification SL Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347- 20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

Further clarifications regarding the scope of this certificate and the applicability of the management system requirements may be obtained by consulting the organisation. To check this certificate validity please refer to the website www.bureauveritas.it

«ERICON» S.R.L.

BUREAU VERITAS
Certification

Allegato al Certificato di Conformità
n° IT280019-3

Subcategory	Active surgical devices	
Generic group	**Model**	**Class**
Electrosurgery, hysteroscopy, nephroscopy, arthroscopy, cystoscopy, resectoscopy and urethrotomy instruments	Arthroscopy instrument, Cystourethroscopy instrument, Hysteroscopy instrument, Nephroscopy instrument, Resectoscopy instrument, Urethrotomy instrument (ref. FT 008 EM Rev. 0 date 05/01/2018)	IIa
	Electrosurgery instrument (ref. FT 008 EM Rev. 0 date 05/01/2018)	IIb

Reference BV practice: ZIG. N. **60526016**

Original cycle start date: **19 March 2018**

Expiry date of previous cycle: **na**

Certification / Recertification Audit date: **04 January 2018**

Certification / Recertification cycle start date: **19 March 2018**

Subject to the continued satisfactory operation of the organization's Management System, this certificate expires on: **18 March 2023**

Certificate No. - Version: IT280019 - 3 Revision date: **20 July 2020**

ANDREA FILIPPI – Certification SL Manager

This certificate is issued by Bureau Veritas Italia S.p.A. Viale Monza, 347-20126 Milan, as a notified body for the Directive 93/42/EEC, with identification number 1370

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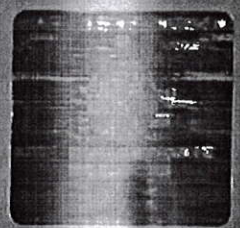

REPUBLICA MOLDOVA, mun. CHIȘINĂU «ERICON» S.R.L. IDNO 1003600000346 SOCIETATEA CU RĂSPUNDERE LIMITATĂ

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE FQA IT280019-3
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

42044016

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
DM000700585	ACCESORIU ENDOSCOP		GRASPING CYSTO-URETHROSCOPI FORCEPS	**42044016**S	Italia	ENDOMED S.R.L.	ERICON S.R.L.	Rg04-000139	31-05-2024
DM000700548	ACCESORIU ENDOSCOP		CYSTO-URETHROSCOPI GRASPING FORCEPS	**42044016**	Italia	ENDOMED S.R.L.	ERICON S.R.L.	Rg04-000139	31-05-2024

Создать фильтр

AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Tip	Denumire
I.3. Certificatul CE	Certificat CE FQA IT280019-3
I.2. Declarația de conformitate CE	Declaratie de conformitate CE

42044023

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data
DM000700586	ACCESORIU ENDOSCOP		GRASPING CYSTO-URETHROSCOPI FORCEPS	**42044023**S	Italia	ENDOMED S.R.L.	ERICON S.R.L.	Rg04-000139	31-05-2024
DM000700549	ACCESORIU ENDOSCOP		CYSTO-URETHROSCOPI GRASPING FORCEPS	**42044023**	Italia	ENDOMED S.R.L.	ERICON S.R.L.	Rg04-000139	31-05-2024

Создать фильтр