



Documentation Review

No. 201013.IMGSD85

Holder: **Ingenious Medical GmbH**
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Review goal: Verification of the presence of Technical Documentation compatible with the Medical Devices Directive 93/42/EEC Annex VII

Product: Trocar System
Intended Purpose: It is designed to use for passing through the abdominal wall and then facilitating the access for the laparoscopic and laparoscopic instruments

Model(s): (see the following annex)

Classification: Class I (Not Sterile according to the Manufacturer's declaration – therefore not requiring NB intervention.)

Review output: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the Technical Documentation shared with us by the manufacturer is compatible with the European Standard for Medical Devices.
The manufacturer is responsible for the CE Marking process, and not exempted to carry out all necessary compliance activities. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01_ECM rev.3 available at: www.entecerma.it

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ECM Service Director
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Ente Certificazione Macchine

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Annex I

No. 201013.IMGSD85

Model(s):

CAT ORDER NO	EN DESCRIPTION
301-101-10	Silicon sealing trocar, 5.5*95mm; pyramidal, un-threaded cannula
301-101-11	Silicon sealing trocar, 5.5*95mm; pyramidal, threaded cannula
301-102-10	Silicon sealing trocar, 5.5*95mm; autoshield, un-threaded cannula
301-102-11	Silicon sealing trocar, 5.5*95mm; autoshield, threaded cannula
301-103-10	Silicon sealing trocar, 5.5*95mm; oblique autoshield, un-threaded cannula
301-103-11	Silicon sealing trocar, 5.5*95mm; oblique autoshield, threaded cannula
302-101-10	Silicon sealing trocar, 10.5*95mm, pyramidal, un-threaded cannula, with 10.5-5.5 reducer
302-101-11	Silicon sealing trocar, 10.5*95mm, pyramidal, threaded cannula, with 10.5-5.5 reducer
302-102-10	Silicon sealing trocar, 10.5*95mm, autoshield, un-threaded cannula, with 10.5-5.5 reducer
302-102-11	Silicon sealing trocar, 10.5*95mm, autoshield, threaded cannula, with 10.5-5.5 reducer
302-103-10	Silicon sealing trocar, 10.5*95mm, oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
302-103-11	Silicon sealing trocar, 10.5*95mm, oblique autoshield, threaded cannula, with 10.5-5.5 reducer
303-101-10	Silicon sealing trocar, 12.5*95mm, pyramidal, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
303-101-11	Silicon sealing trocar, 12.5*95mm, pyramidal, threaded cannula with 12.5-10.5/12.5-5.5 reducer
303-102-10	Silicon sealing trocar, 12.5*95mm, autoshield, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
303-102-11	Silicon sealing trocar, 12.5*95mm, autoshield, threaded cannula with 12.5-10.5/12.5-5.5 reducer
303-103-10	Silicon sealing trocar, 12.5*95mm, oblique autoshield, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
303-103-11	Silicon sealing trocar, 12.5*95mm, oblique autoshield, threaded cannula with 12.5-10.5/12.5-5.5 reducer
300-500-244	Ø3 mm Silicon sealing trocar with pyramidal tip and length 95 mm
304-101-10	Magnetic ball trocar, 5.5*95mm; pyramidal, un-threaded cannula
304-101-11	Magnetic ball trocar, 5.5*95mm; pyramidal, threaded cannula
304-102-10	Magnetic ball trocar, 5.5*95mm; autoshield, un-threaded cannula
304-102-11	Magnetic ball trocar, 5.5*95mm; autoshield, threaded cannula
304-103-10	Magnetic ball trocar, 5.5*95mm; oblique autoshield, un-threaded cannula
304-103-11	Magnetic ball trocar, 5.5*95mm; oblique autoshield, threaded cannula
305-101-10	Magnetic ball trocar, 10.5*95mm; pyramidal, un-threaded cannula, with 10.5-5.5 reducer
305-101-11	Magnetic ball trocar, 10.5*95mm; pyramidal, threaded cannula, with 10.5-5.5 reducer
305-102-10	Magnetic ball trocar, 10.5*95mm; autoshield, un-threaded cannula, with 10.5-5.5 reducer
305-102-11	Magnetic ball trocar, 10.5*95mm; autoshield, threaded cannula, with 10.5-5.5 reducer
305-103-10	Magnetic ball trocar, 10.5*95mm; oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
305-103-11	Magnetic ball trocar, 10.5*95mm; oblique autoshield, threaded cannula, with 10.5-5.5 reducer
306-101-10	Manual lever trocar, 5.5*95mm; pyramidal, un-threaded cannula
306-101-11	Manual lever trocar, 5.5*95mm; pyramidal, threaded cannula
306-102-10	Manual lever trocar, 5.5*95mm; autoshield, un-threaded cannula
306-102-11	Manual lever trocar, 5.5*95mm; autoshield, threaded cannula
306-103-10	Manual lever trocar, 5.5*95mm; oblique autoshield, un-threaded cannula
306-103-11	Manual lever trocar, 5.5*95mm; oblique autoshield, threaded cannula
307-101-10	Manual lever trocar, 10.5*95mm, pyramidal, un-threaded cannula, with 10.5-5.5 reducer
307-101-11	Manual lever trocar, 10.5*95mm, pyramidal, threaded cannula, with 10.5-5.5 reducer
307-102-10	Manual lever trocar, 10.5*95mm, autoshield, un-threaded cannula, with 10.5-5.5 reducer
307-102-11	Manual lever trocar, 10.5*95mm, autoshield, threaded cannula, with 10.5-5.5 reducer
307-103-10	Manual lever trocar, 10.5*95mm, oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
307-103-11	Manual lever trocar, 10.5*95mm, oblique autoshield, threaded cannula, with 10.5-5.5 reducer
308-101-10	Manual lever trocar, 12.5*95mm, pyramidal, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
308-101-11	Manual lever trocar, 12.5*95mm, pyramidal, threaded cannula with 12.5-10.5/12.5-5.5 reducer
308-102-10	Manual lever trocar, 12.5*95mm, autoshield, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
308-102-11	Manual lever trocar, 12.5*95mm, autoshield, threaded cannula with 12.5-10.5/12.5-5.5 reducer
308-103-10	Manual lever trocar, 12.5*95mm, oblique autoshield, un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
308-103-11	Manual lever trocar, 12.5*95mm, oblique autoshield, threaded cannula with 12.5-10.5/12.5-5.5 reducer
309-101-10	Magnetic sheet trocar, 5.5*95mm; pyramidal, un-threaded cannula
309-101-11	Magnetic sheet trocar, 5.5*95mm; pyramidal, threaded cannula
309-102-10	Magnetic sheet trocar, 5.5*95mm; autoshield, un-threaded cannula
309-102-11	Magnetic sheet trocar, 5.5*95mm; autoshield, threaded cannula
309-103-10	Magnetic sheet trocar, 5.5*95mm; oblique autoshield, un-threaded cannula
309-103-11	Magnetic sheet trocar, 5.5*95mm; oblique autoshield, threaded cannula
310-101-10	Magnetic sheet trocar, 10.5*95mm; pyramidal, un-threaded cannula, with 10.5-5.5 reducer
310-101-11	Magnetic sheet trocar, 10.5*95mm; pyramidal, threaded cannula, with 10.5-5.5 reducer
310-102-10	Magnetic sheet trocar, 10.5*95mm; autoshield, un-threaded cannula, with 10.5-5.5 reducer

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310-102-11	Magnetic sheet trocar, 10.5*95mm; autoshield, threaded cannula, with 10.5-5.5 reducer
310-103-10	Magnetic sheet trocar, 10.5*95mm; oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
310-103-11	Magnetic sheet trocar, 10.5*95mm; oblique autoshield, threaded cannula, with 10.5-5.5 reducer
311-101-10	Magnetic sheet trocar, 12.5*95mm, pyramidal un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
311-101-11	Magnetic sheet trocar, 12.5*95mm, pyramidal threaded cannula with 12.5-10.5/12.5-5.5 reducer
311-102-10	Magnetic sheet trocar, 12.5*95mm, autoshield; un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
311-102-11	Magnetic sheet trocar, 12.5*95mm, autoshield; threaded cannula with 12.5-10.5/12.5-5.5 reducer
311-103-10	Magnetic sheet trocar, 12.5*95mm, oblique autoshield; un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
311-103-11	Magnetic sheet trocar, 12.5*95mm, oblique autoshield; threaded cannula with 12.5-10.5/12.5-5.5 reducer
313-101-10	Magnetic sheet trocar, 12.5*150mm, pyramidal un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
316-101-11	Magnetic sheet trocar, 12.5*150mm, pyramidal threaded cannula with 12.5-10.5/12.5-5.5 reducer
316-102-10	Magnetic sheet trocar, 12.5*150mm, autoshield; un-threaded cannula with 12.5-10.5/12.5-5.5 reducer
317-102-10	Magnetic sheet trocar, 15*150mm, autoshield; un-threaded cannula
312-101-10	Manual lever trocar, 5.5*95mm; pyramidal, un-threaded cannula
312-101-11	Manual lever trocar, 5.5*95mm; pyramidal, threaded cannula
312-102-10	Manual lever trocar, 5.5*95mm; autoshield, un-threaded cannula
312-102-11	Manual lever trocar, 5.5*95mm; autoshield, threaded cannula
312-103-10	Manual lever trocar, 5.5*95mm; oblique autoshield, un-threaded cannula
312-103-11	Manual lever trocar, 5.5*95mm; oblique autoshield, threaded cannula
313-101-10	Manual lever trocar, 6*95mm; pyramidal, un-threaded cannula
313-101-11	Manual lever trocar, 6*95mm; pyramidal, threaded cannula
313-102-10	Manual lever trocar, 6*95mm; autoshield, un-threaded cannula
313-102-11	Manual lever trocar, 6*95mm; autoshield, threaded cannula
313-103-10	Manual lever trocar, 6*95mm; oblique autoshield, un-threaded cannula
313-103-11	Manual lever trocar, 6*95mm; oblique autoshield, threaded cannula
314-101-10	Manual lever trocar, 10.5*95mm; pyramidal, un-threaded cannula, with 10.5-5.5 reducer
314-101-11	Manual lever trocar, 10.5*95mm; pyramidal, threaded cannula, with 10.5-5.5 reducer
314-102-10	Manual lever trocar, 10.5*95mm; autoshield, un-threaded cannula, with 10.5-5.5 reducer
314-102-11	Manual lever trocar, 10.5*95mm; autoshield, threaded cannula, with 10.5-5.5 reducer
314-103-10	Manual lever trocar, 10.5*95mm; oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
314-103-11	Manual lever trocar, 10.5*95mm; oblique autoshield, threaded cannula, with 10.5-5.5 reducer
315-101-10	Manual lever trocar, 11*95mm; pyramidal, un-threaded cannula, with 10.5-5.5 reducer
315-101-11	Manual lever trocar, 11*95mm; pyramidal, threaded cannula, with 10.5-5.5 reducer
315-102-10	Manual lever trocar, 11*95mm; autoshield, un-threaded cannula, with 10.5-5.5 reducer
315-102-11	Manual lever trocar, 11*95mm; autoshield, threaded cannula, with 10.5-5.5 reducer
315-103-10	Manual lever trocar, 11*95mm; oblique autoshield, un-threaded cannula, with 10.5-5.5 reducer
315-103-11	Manual lever trocar, 11*95mm; oblique autoshield, threaded cannula, with 10.5-5.5 reducer
300-100-00	Reducer 10.5 - 5.5*100mm
300-100-01	Reducer 10.5 - 5.5*120mm
300-100-02	Reducer 10.5 - 5.5*150mm
300-100-03	Reducer 10.5 - 5.5*180mm
300-100-04	Reducer adapter 10.5 - 5.5
300-100-05	Reducer adapter 10.5 - 5.5
300-100-25	Reducer 12.5-5.5*100mm
300-100-26	Reducer 12.5-5.5*150mm
300-100-27	Reducer 12.5-5.5*180mm
300-100-28	Reducer 12.5-10.5*100mm
300-100-29	Reducer 12.5-10.5*80mm
300-100-30	Reducer 12.5-10.5*180mm
300-100-31	Reducer 15-5.5*80mm
300-100-32	Reducer 15-5.5*150mm
300-100-33	Reducer 15-10.5*30mm
300-100-34	Reducer adapter 12.5 - 5.5 for magnetic sheet trocar
300-100-35	Reducer adapter 12.5 - 10.5 for magnetic sheet trocar
300-100-36	Reducer adapter 10.5 - 5.5 for magnetic sheet trocar
300-100-37	Reducer adapter 15 - 5.5 for magnetic sheet trocar
300-100-38	Reducer adapter 15 - 10.5 for magnetic sheet trocar
300-100-06	Sealing Cap 3mm
300-100-07	Sealing Cap 5mm
300-100-08	Sealing Cap 10mm
300-100-09	Sealing Cap 12mm
300-100-39	Sealing Caps 15mm
300-100-10	Veress needle 2.2*110mm
300-100-11	Veress needle 2.2*120mm
300-100-12	Veress needle 2.2*150mm
300-100-13	Connector (Small)
300-100-14	Connector (Medium)