



Documentation Review

No. 201013.IMGSD88

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: Needle Holder
Intended Purpose: To hold the needle for tissue stitching during the surgery.
Knot Pusher
Intended purpose: To push knot Sutures during surgery.
(see the following annex)

Model(s):

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

Date of issue 15 October 2020

Approver
ECM Service Director
Luca Bedonni

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Annex I

No. 201013.IMGSD88

Model(s):

CAT ORDER NO	EN DESCRIPTION
300-300-00	Needle holder; O Shape Ø5x330mm, Straight
300-300-01	Needle holder; O Shape Ø5x330mm, Curved
300-300-02	Needle holder; O Shape Ø5x330mm, Self-righting
300-300-03	Needle holder; O Shape Ø5x330mm, Self-righting
300-300-04	Needle holder; O Shape Ø5x330mm, Self-righting
300-300-05	Needle holder; Pistol Ø5x330mm, Straight
300-300-06	Needle holder; Pistol Ø5x450mm, Straight
300-300-07	Needle holder; Pistol Ø5x330mm, Curved
300-300-08	Needle holder; Pistol Ø5x450mm, Curved
300-300-09	Needle holder; Pistol Ø5x330mm, Curved to right
300-300-10	Needle holder; Pistol Ø5x450mm, Curved to right
300-300-11	Needle holder; Pistol Ø5x330mm, Self-righting
300-300-12	Needle holder; Pistol Ø5x450mm, Self-righting
300-300-13	Needle holder; Pistol Ø5x330mm, Self-righting
300-300-14	Needle holder; Pistol Ø5x450mm, Self-righting
300-300-15	Needle holder; Pistol Ø5x330mm, Self-righting
300-300-16	Needle holder; Pistol Ø5x450mm, Self-righting
300-300-17	Needle holder; A Shape, Vertical Ø5x330mm, Straight
300-300-18	Needle holder; A Shape, Vertical Ø5x330mm, Curved
300-300-19	Needle holder; A Shape, Vertical Ø5x330mm, Self-righting
300-300-20	Needle holder; A Shape, Vertical Ø5x330mm, Self-righting
300-300-21	Needle holder; A Shape, Vertical Ø5x330mm, Self-righting
300-300-22	Needle holder; V Shape Ø5x330mm, Straight
300-300-23	Needle holder; V Shape Ø5x450mm, Straight
300-300-24	Needle holder; V Shape Ø5x330mm, Curved
300-300-25	Needle holder; V Shape Ø5x450mm, Curved
300-300-26	Needle holder; V Shape Ø5x330mm, Elbow to right
300-300-27	Needle holder; V Shape Ø5x450mm, Elbow to right
300-300-28	Needle holder; V Shape Ø5x330mm, Self-righting
300-300-29	Needle holder; V Shape Ø5x450mm, Self-righting
300-300-30	Needle holder; V Shape Ø5x330mm, Self-righting
300-300-31	Needle holder; V Shape Ø5x330mm, Self-righting
300-300-32	Needle holder; V Shape Ø5x330mm, Straight Detachable
300-500-245	O shape needle holder straight Ø3x300mm
300-500-246	O shape needle holder curved Ø3x300mm
300-500-247	A shape needle holder straight Ø3x300mm
300-500-248	A shape needle holder curved Ø3x300mm
300-300-33	Knot Pusher, Without Suture Opening, Ø5x330mm
300-300-34	Knot Pusher, With Suture Opening, Ø5x330mm
300-300-35	Knot Pusher, With Suture Opening, Ø5x450mm
	2.8 and 3.0 Not Available