



Documentation Review

No. 201013.IMGSD87

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: Clip Appliers
Intended Purpose: Used to deliver and close a ligating clip to ligate vascular or structure during laparoscopic surgery.

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

Date of issue 13 October 2020

Approver
ECM Service Director
Luca Becchini



Expiry date 12 October 2025

Technical Expert
Antonio Payne



Annex I

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Model(s):

Order No.	Description
300-200-03	Clip Applier Ø10x330mm
300-200-04	Clip Applier Ø10x330mm (Detachable)
300-200-05	Clip Applier Ø10x250mm for open surgery
300-200-06	Clip Applier Ø10x330mm
300-200-07	Clip Applier Ø10x330mm (Detachable)
300-200-09	Clip Applier Ø5x330mm
300-200-10	Clip Applier Ø5x330mm (Detachable)
300-200-21	For L Polymer clips, Ø5.5x330mm
300-200-26	Single Action Clip applier L
300-200-27	Single Action Clip applier ML
300-200-28	Single Action Clip applier L, detachable
300-200-29	Single Action Clip applier ML, detachable
300-200-30	Single Action Clip applier M
300-200-31	Single Action Clip applier S
300-200-32	Degree 90° Clip applier ML
300-200-33	Degree 90° Clip applier ML, detachable
300-200-34	Double Action Clip applier L
300-200-35	Double Action Clip applier ML
300-200-36	Double Action Clip applier L, detachable
300-200-37	Double Action Clip applier ML, detachable
300-200-00	Clip applier part
300-200-01	Clip applier part
300-200-02	Clip applier part
300-200-22	Clip applier part
300-200-23	Clip applier part
300-200-24	Clip applier part
300-200-25	Clip applier part for 5mm clip appliers