



Documentation Review

No. 201013.IMGSD89

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: Closure Forceps
Intended Purpose: Used for suture of surgical incision or peritoneal during 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

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Approver
ECM Service Director
Luca Bodonni



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Annex I

No. 201013.IMGSD89

Model(s):

CAT ORDER NO	EN DESCRIPTION
300-300-36	Closure Forceps, Ø2.5mm
300-300-37	Closure Forceps, Ø2.5mm Up Open
300-300-38	Closure Forceps, Ø2.5mm Down Open
300-300-39	Closure Forceps, Ø1.5mm
300-300-40	Closure Forceps
300-300-41	Closure Forceps, Ø2.2mm

