Review Report –审查报告–검토 보고서– Rapport d'Evaluation

Documentation Review

No. 201013.IMGSD90

Holder: Ingenious Medical GmbH
79106 Freiburg im Breisgau, Germany
Phone: +49(0)761-15521831
Email: info@ingenious-medical.de
Website: www.ingenious-medical.de

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

Product: Retractors
Intended Purpose: To provide excellent exposure for tissue.

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 15 October 2020
Approver
ECM Service Director
Luca Bedonni

Expiry date 12 October 2025

Technical Expert
Amanda Payne

Annex I

No. 201013.IMGSD90

Model(s):

CAT ORDER NO	EN DESCRIPTION
300-400-00	Kite-shaped, Ø5x350mm
300-400-01	Fan-shaped, Ø5x350mm
300-400-02	Fan-shaped, Ø5x350mm
300-400-03	Articulating, Ø10x350mm
300-400-04	Fan-shaped, Ø10x350mm
300-400-05	Golden Finger, Ø5.5x460mm
300-400-06	Golden Finger; Half Ring Ø5.5x460mm
300-400-07	Golden Finger; Full Ring (Down) Ø5.5x460mm
300-400-08	Golden Finger; Full Ring (Up) Ø5.5x460mm
300-400-09	Retractor