



Documentation Review

No. 201013.IMGSD86

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: Aspiration Device
Intended Purpose: Used for infusion and extraction during operation

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 Bedonni



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Annex I

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Model(s):

Order No.	Description
300-100-15	Aspiration device 5*330mm; 1.2 mm tip
300-100-16	Aspiration device 5*330mm; 0.7 mm tip
300-100-17	Aspiration device 5*330mm; 0.9 mm tip
300-100-18	Aspiration device 5*330mm; 1.6 mm tip
300-100-19	Aspiration device 5*330mm; 1.8 mm tip
300-100-20	Aspiration device 5*330mm; 2 mm tip
300-100-21	Aspiration device 5*330mm; 2.2 mm tip
300-600-08	Aspiration device 5*330mm; 2.4 mm tip
300-600-09	Aspiration device 5*330mm; 2.5 mm tip
300-600-10	Aspiration device 5*330mm; 2.6 mm tip
300-600-11	Aspiration device 5*330mm; 2.8 mm tip
300-600-12	Aspiration device 5*330mm; 2.9 mm tip
300-600-13	Aspiration device 5*330mm; 2.95 mm tip
300-500-14	Aspiration device 5*330mm; 3 mm tip
300-500-15	Aspiration device 5*330mm; 3.1 mm tip
300-500-16	Aspiration device 5*330mm; 3.3 mm tip
300-500-17	Aspiration device 5*330mm; 3.4 mm tip
300-500-18	Aspiration device 5*330mm; 3.5 mm tip