



## Certificate of Conformance

Certificate Number: EXMXJ3702X98 Dated Issued: 11/17/2021

The blades were produced in accordance with Exsurco current design specification using only approved manufacturing processes and conforms to all established quality inspection and test criteria.<sup>1</sup>

Product Item Number:	X100593
Item Description:	PACK, AMALGATOME SK HEAD, 5 PC
Item Lot Number:	X-000000000098
Expiration Date:	2023-10

The blades were manufactured using a validated sterilization process:

STERIS Gamma Process Run ID:	1073-6325A		
Processing Run Date:	01-Nov-2021		
Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	28.2
Maximum Specified Dose (kGy):	45.0	Maximum Delivered Dose (kGy):	38.7

Exsurco Medical is an ISO 13485:2016 certified and an FDA registered company. Exsurco Medical is committed to a policy of **QUALITY WITHOUT COMPROMISE**.

Quality Department

Quality Manager

11/17/2.

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 $<sup>^{\</sup>mbox{\tiny 1}}$  Manufacturing data filed within the Quality Management System and available onsite.