



## Certificate of Conformance

Certificate Number: EXMXJ3193X65 Dated Issued: 09/03/2020

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-000000000065
Expiration Date:	2022/08

The blades were manufactured using a validated sterilization process:

STERIS Gamma Process Run ID:	11142	2A	
Processing Run Date:	28-Aug-2020		
Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	28.9
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

091031202

Date

09-03-2020

Date

<sup>&</sup>lt;sup>1</sup> Manufacturing data filed within the Quality Management System and available onsite.