



## Certificate of Conformance

Certificate Number: EXMXJ3372X70

Dated Issued: 02/04/2021

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>

<b>Product Item Number:</b>	X100593
<b>Item Description:</b>	Pack, Amalgatome SK head, 5 pc
<b>Item Lot Number:</b>	X-0000000000070
<b>Expiration Date:</b>	2022/12


The blades were manufactured using a validated sterilization process:

<b>STERIS Gamma Process Run ID:</b>	1073-2135A		
<b>Processing Run Date:</b>	01-Feb-2021		
<b>Minimum Specified Dose (kGy):</b>	25.0	<b>Minimum Delivered Dose (kGy):</b>	27.1
<b>Maximum Specified Dose (kGy):</b>	45.0	<b>Maximum Delivered Dose (kGy):</b>	39.5

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

  
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 Quality Department

2/4/21  
 \_\_\_\_\_  
 Date

  
 \_\_\_\_\_  
 Quality Manager

02/09/2021  
 \_\_\_\_\_  
 Date

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