



Certificate of Conformance

Certificate Number: EXMXJ3221X66 Dated Issued: 11/10/2020

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.¹

Product Item Number:	X100593	
Item Description:	Pack, Amalgatome SK head, 5 pc	
Item Lot Number:	X-000000000066	
Expiration Date:	2022/08	

The blades were manufactured using a validated sterilization process:

STERIS Gamma Process Run ID:	11182	7A		
Processing Run Date:	03-0c	03-Oct-2020		
Minimum Specified Dose (kGy):	25.0	Minimum Delivered Dose (kGy):	26.8	
Maximum Specified Dose (kGy):	45.0	Maximum Delivered Dose (kGy):	38.1	

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

Date

Date

11-10-2020.

Date

 $^{^{\}rm 1}$ Manufacturing data filed within the Quality Management System and available onsite.