

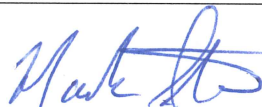


Danville



ZEST | DANVILLE MATERIALS | PERIOSCOPY

DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	Danville Materials 2875 Loker Avenue East Carlsbad, CA 92010 USA	
AUTHORIZED REPRESENTATIVE	MDSS GmbH Schiffgraben 41 30175 Hannover, GERMANY	
RESPONSIBILITY	This declaration of conformity is issued under the sole responsibility of Danville Materials	
PRODUCT(S)	MicroEtcher (refer to attached product schedule)	
RISK CLASS	Class I	
CONFORMITY ASSESSMENT ROUTE	Annex VII	
DECLARATION	We, the manufacturer, Danville Materials, declare that the above mentioned product meets the provision of Council Directive 93/42/EEC for Medical Devices	
NOTIFIED BODY	N/A – not applicable to Class I devices	
EC CERTIFICATE	N/A – not applicable to Class I devices	
STANDARDS APPLIED	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
	ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
	EN ISO 15223-1:2016	Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements
	EN 1041:2008	Information supplied by the manufacturer of medical devices
PLACE OF ISSUE	Carlsbad, CA, USA	
SIGNED		
	Mark Stavro, Director Regulatory Affairs	August 16, 2018 Date



Part Number	Description	GMDN Code	UMDNS Code
21000-03	MICROETCHER ERC	45403	11-161
22006	SAND TRAP Kit, Qty 15	45403	11-161
15201	ALUMINUM OXIDE 90 Micron Tan	45407	17-737
80042A	ALUMINUM OXIDE 27 Micron White	45407	17-737
15301	ALUMINUM OXIDE 50 Micron White	45407	17-737
16101	GLASS BEADS	45407	17-737
17011	MICROPROPHY B	45407	17-737
14001	ORTHOPROPHY SA-85	45407	17-737
44000	1/4 MALE QD WITH PLASTIC TEE	45406	11-161
44007	MALE LAB QUICK DISCONNECT	45406	11-161
44010	1/4 FEMALE QD WITH PLASTIC TEE	45406	11-161
44017	KIT,QD,LAB,2ND STATION	45406	11-161
44020	QUICK DISCONNECT MALE	45406	11-161
44075	ADAPTER, HOOK UP, 4 HOLE	45406	11-161
201431-00	ASSY, CONNECTOR, KAVO	45406	11-161