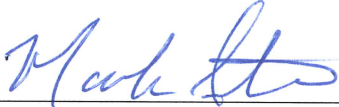





DECLARATION OF CONFORMITY

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 IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II	
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	BSI (NB# 0086) Kitemark Court Davy Avenue, Knowlhill Milton Keynes, Mk5 8PP United Kingdom	
EC CERTIFICATE	CE 598352 Expiry Date: 18 June 2023	
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
	ISTA-6-FedEx-A	Testing Packaged Products Weighing up to 150 Lbs
PLACE OF ISSUE	Carlsbad, CA, USA	
SIGNED	<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <hr/> Mark Stavro, Director Regulatory Affairs </div> <div style="text-align: center;">  <hr/> Date </div> </div>	



Danville

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Part Number	Description	GMDN Code	UMDNS Code
22000-03	MICROETCHER II	45403	11-161
93853	MICROETCHER II, LEFT-HANDED	45403	11-161
22005-01	MICROETCHER IIA	45403	11-161
93825	MICROETCHER CN BIEN-AIR	45403	11-161
201936-00	MICROETCHER CD KAVO	45403	11-161
201935-00	MICROETCHER CD SIRONA	45403	11-161
201802-00	ASSY, NOZ, MICROETCHER II	45131	26-864
201865-00	ASSY, NOZ, MICROETCHER IIA	45131	26-864
186113	PIT & FISSURE NOZZLE, 0.032/60 DEG.	45131	26-864