



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)	Air Abrasion (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
PLACE OF ISSUE	Carlsbad, CA, USA	
SIGNED	 <hr/> Mark Stavro, Director Regulatory Affairs	
		<hr/> April 2, 2018 Date



Part Number	Description	GMDN Code	UMDNS Code
200259-00	PREPSTART	45403	11-161
91747	PREPSTART,H2O	45403	11-161
91913	PREPSTART,H2O,ATTACHMENT KIT	45403	11-161
93383	POWER,PLUS,AIR BOOSTER,FINAL	45403	11-161
200628	PREPSTART,HANDPIECE KIT 1	45403	11-161
200567	PREPSTART,HANDPIECE KIT 2	45403	11-161
200308-00	HANDPIECE KIT, PREPSTART	45403	11-161
92944	H2O HANDPIECE ASSEMBLY	45403	11-161
91720	ASSY,SHOP,HANDPIECE&.019NOZZLE	45131	11-161
91736	ASSY,NOZ,019,PS H2O	45131	11-161
91736-01	ASSY,NOZ,015,PS H2O	45131	11-161
186934-01	KIT,NOZ,.019/80DEG(3)D.E.	45131	26-864
186937-01	KIT,NOZ,.015/80DEG(3)D.E.	45131	26-864
28515	NOZZLE ASSY,0.015/45 DEG	45131	26-864
28519	NOZZLE ASSY,0.019/45 DEG	45131	26-864
28520	NOZZLE ASSY,0.015/90 DEG	45131	26-864
28521	NOZZLE ASSY,0.015/120 DEG	45131	26-864
28526	NOZZLE ASSY,0.026/45 DEG	45131	26-864
28527	NOZZLE ASSY,0.019/80 DEG	45131	26-864
28528	NOZZLE ASSY,0.015/80 DEG	45131	26-864
28529	NOZZLE ASSY,0.026/80 DEG	45131	26-864
28530	NOZZLE ASSY,0.019/90 DEG	45131	26-864
28531	NOZZLE ASSY,0.019/120 DEG	45131	26-864
28540	NOZZLE ASSY,0.026/90 DEG	45131	26-864
28541	NOZZLE ASSY,0.026/120 DEG	45131	26-864