Danville

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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)	MicroProphy II (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 13485:2012	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
	ISO 15223-1:2012	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
	EN 980:2008	Symbols for use in the labelling of medical devices
PLACE OF ISSUE	Carlsbad, CA, USA	
SIGNED	Mark Stavro, Director Regulatory Affairs	May 25, 2017 Date

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Part Number	Description	GMDN Code	UMDNS Code
201684-00	MICROPROPHY II	45403	11-161
23523	NOZZLE .023 STAINLESS STEEL	45131	26-864
23526	NOZZLE .026 CARBIDE	45131	26-864
23623	NOZZLE .023	45131	26-864
23626	NOZZLE .026	45131	26-864
17001	M-PRO B PLUS SOD BI, 1LB	45407	17-737