Danville

ZD ZEST DENTAL SOLUTIONS

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)	Microprime G (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	Mark Stavro, Director Regulatory Affairs	April 2, 2019 Date

Part Number	Description	GMDN Code	UMDNS Code
10148	MICROPRIME G, SAMPLE	45232	11-184
90814	MICROPRIME G,10ML	45232	11-184
94178	MICROPRIME G,SMPL,UD,0.2ML(2)	45232	11-184
94263	MICROPRIME G UNIT DOSE 50 PCS	45232	11-184
90-00091	MICROPRIME G 5ML SAMPLE	45232	11-184