




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)	Impression Materials (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	11/20/2017 Date

Part Number	Description	GMDN Code	UMDNS Code
89331-00	DISPENSER GUN	35697	27-448
80016	START VPS,PUTTY KIT	34799	27-374
89272	1ST QTR,FS, LT.BODY,4 PACK	34799	27-374
89277	1ST QTR,FS,LT.BODY,2 KIT	34799	27-374
89386	1ST QTR,F.S,MONOPHASE,2	34799	27-374
89387	1ST QTR,FS,MONOPHASE,4 PACK	34799	27-374
89462	1ST QTR,LT.BODY,ECONO KIT	34799	27-374
90133	CART,PONTIC,A1,25ML	34799	27-374
90467	1ST HALF,LT.BODY,BLACK,2 PACK	34799	27-374
90468	1ST HALF,LT.BODY,BLACK,4PK	34799	27-374
90469	1ST HALF,LT.BDY,BLK,ECONO(24)	34799	27-374
90648	1ST HALF,H-BODY,LIME GREEN,2PK	34799	27-374
90649	1ST HALF,H-BODY,LIME GREEN,4PK	34799	27-374
90650	1ST HALF,H-BODY,GREEN,ECONO PK	34799	27-374
90727	START VPS, LIGHT, S-ECONO (96)	34799	27-374
90728	START VPS,HVY,FLX,S-ECONO (96)	34799	27-374
90729	1ST QTR,FS,MONOPHASE,SE	34799	27-374
90730	START VPS,HVY,STIFF,SUPER (96)	34799	27-374
90731	1ST QTR,FS, LT.BODY,SE	34799	27-374
90732	START VPS, HVY,BODY,SUPER (96)	34799	27-374
90733	LIGHT BODY BLACK SUPER ECONO (96)	34799	27-374
90809	1ST QUARTER,HEAVY,4 PACK	34799	27-374
90810	1ST QUARTER,HEAVY,ECONO KIT	34799	27-374
90811	1ST QUARTER,HEAVY,SE	34799	27-374
90900	1ST QTR,MONO,FS,CHOC/MINT(4)	34799	27-374
90901	1ST QTR.MONOPHASE,CHOCMNT.2	34799	27-374
90902	1ST QTR,MONO,FS,CHOC/MINT,ECON	34799	27-374
90903	1ST QTR,MONO,FS,CHOC/MINT,SE	34799	27-374
90913	1ST QUARTER,HEAVY,2 PACK	34799	27-374
91122	1ST HALF,MONOPHASE,2 PACK	34799	27-374
91123	1ST HALF,MONOPHASE,4 PACK	34799	27-374
91124	1ST HALF,MONOPHASE,ECONO KIT	34799	27-374
91125	MONOPHASE ORTHO SUPER ECONO (96)	34799	27-374
91241	1ST HALF,LT BODY,ORANGE,2 PK	34799	27-374
91242	1ST HALF,LT BODY,ORANGE,4 PK	34799	27-374
91243	1ST HALF,LT,BODY,ORANGE,(24)	34799	27-374
91244	LIGHT BODY ORANGE SUPER ECONO (96)	34799	27-374
93133	1ST HALF,PUTTY KIT,FAST SET	34799	27-374
93717	STAR VPS,VANILLA KIT 2	34799	27-374
93718	VANILLA BITE ECONO (24)	34799	27-374
94260	STARVPS, UD, LT. BODY, ORANGE, FH (40)	34799	27-374
80006-01	START VPS,HEAVY,STIFF,ECON KIT	34799	27-374
80007-01	START VPS,HEAVY,FLEX,ECON KIT	34799	27-374
80008-01	1ST QUARTER,MONO,ECON KIT,FA	34799	27-374
80009-01	START VPS,LT.BODY.ECONO KIT	34799	27-374
80011-01	START VPS,LT,BODY KIT 4	34799	27-374



Part Number	Description	GMDN Code	UMDNS Code
80013-01	START VPS,HEAVY,FLEX,KIT(4),FA	34799	27-374
80014-01	START VPS,HEAVY,STIFF KIT (4)	34799	27-374
80015-01	START VPS,CLEAR KIT (4)	34799	27-374
80021-01	START VPS,LT,BODY KIT 2	34799	27-374
80023-01	START VPS,HEAVY,FLEX,KIT 2	34799	27-374
80024-01	START VPS,HEAVY,STF,BITE,KIT 2	34799	27-374
80025-01	START VPS,CLEAR BITE,KIT 2	34799	27-374
80037-01	STAR VPS,CLEAR BITE,ECONO KIT	34799	27-374
80060-01	START VPS,ULTRA,LT.KIT(4)	34799	27-374
80061-01	START VPS,ULTRA,LT.ECONO KIT	34799	27-374
80062-01	START VPS,ULTRA,HEAVY,KIT(4)	34799	27-374
80065-01	START VPS,ULTRA,HEAVY,ECON	34799	27-374
93735	MOJO II SYRINGES 100PK	58399	26-864
93761	MOJO MIXING TIP W/IOT (50)	58399	26-864
93966	MOJO II, SAMPLE,4 PACK	58399	26-864
89389	MIXING TIP, WASTE SAVER, BLUE LIGHT BODY (12)	58399	26-864
90002	MIXING TIP, TEAL (12)	58399	26-864
90003	MIXING TIP,WASTE SAVER, TEAL (48)	58399	26-864
90715	MIXER, ERGOTIP, PURPLE, (48)	58399	26-864
93112	WASTE SAVER, BLUE MIXER TIP, LIGHT BODY (12)	58399	26-864
93113	WASTE SAVER, BLUE MIXER TIP, LIGHT BODY (48)	58399	26-864
94212	INTRAORAL TIP, YELLOW (48)	38795	26-864
91667	TRAY,LINK,ADHESIVE	16658	16-658