




DECLARATION OF CONFORMITY

LEGAL MANUFACTURER	Zest Anchors, LLC 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 Zest Anchors, LLC.	
PRODUCT(S)	LOCATOR Abutment Attachment System (refer to attached product schedule)	
RISK CLASS	Class IIa	
CONFORMITY ASSESSMENT ROUTE	Annex II	
DECLARATION	We, the manufacturer, Zest Anchors, LLC, declare that the above mentioned product meets the provision of Council Directive 93/42/EEC for Medical Devices.	
NOTIFIED BODY	BSI (NB# 2797) Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	
EC CERTIFICATE	CE 598352	
STANDARDS APPLIED	EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
	ISO 10933-1:2020	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+A1:2018	Information supplied by the manufacturer of medical devices
PLACE OF ISSUE	Carlsbad, CA, USA	
SIGNED	<div style="text-align: center;">    <hr/> Maleata Hall, Director Regulatory Affairs </div> <div style="text-align: center; margin-top: 10px;"> I approve this document Dec 11, 2023 11:19:58 AM PST </div>	

Part Number	Description	GMDN Code	UMDNS Code
08510	LOC REPL DENT CAP MALE ASSY (4PK)	44879	23876
08519	LOCATOR Male Processing Package	44879	23876
08520-SB	LOCATOR® 0 Degree Female (1 Pack)	44879	23876
08521-SB	LOCATOR® 10 Degree Female (1 Pack)	44879	23876
08522-SB	LOCATOR® 20 Degree Female (1 Pack)	44879	23876
08524-01	LOCATOR REPLC MALE CLEAR	44879	23876
08524	LOCATOR REPLC MALE CLEAR (4 PACK)	44879	23876
08527-01	LOCATOR LIGHT RET REPL ML PINK	44879	23876
08527	LOCATOR LIGHT RET REPL ML PINK 4PK	44879	23876
08529-01	LOC XTRA LIGHT RET MALE(BLUE) (4PK)	44879	23876
08529	LOC XTRA LIGHT RET MALE(BLUE) (4PK)	44879	23876
08540	LOCATOR Extended Range Male Processing Package	44879	23876
08547-01	LOC EXTD RANGE REPL MALE GREEN 4PK	44879	23876
08547	LOC EXTD RANGE REPL MALE GREEN 4PK	44879	23876
08548-01	LOC,EX LT RET,EXT RNG MALE(RED)	44879	23876
08548	LOC,EX LT RET,EXT RNG MALE(RED) 4PK	44879	23876
08558-01	LOC ZERO RET EXT RNG GRAY MALE 4PK	44879	23876
08558	LOC ZERO RET EXT RNG GRAY MALE 4PK	44879	23876
08559	LOCATOR High Retention Nylon Male, Purple	44879	23876
08915	LOC EXT RANGE REPL MALE ORANGE 4PK	44879	23876
08510-10	LOC REPL DENT CAP MALE ASSY (10PK)	44879	23876
08519-10	LOCATOR MALE PROCESSING PKG(10PACK)	44879	23876
08519-2	LOCATOR MALE PROCESSING PKG (2PACK)	44879	23876
08524-20	LOCATOR REPLC MALE CLEAR (20 PACK)	44879	23876
08527-20	LOCATOR LIGHT RET REPL ML PINK 20PK	44879	23876
08529-20	LOC XTRA LIGHT RET MALE(BLUE)(20PK)	44879	23876
08540-10	LOCATOR Extended Range Male Processing Package (10 pack)	44879	23876
08540-2	LOCATOR Extended Range Male Processing Package (2 pack)	44879	23876
08547-20	LOC EXTD RANGE REPL MALE GREEN 20PK	44879	23876
08548-20	LOC,EX LT RET,EXT RNG MALE,RED,20PK	44879	23876
08550-2	LOCATOR Male Processing Package, SS (2 Pack)	44879	23876
08558-20	LOC ZERO RET EXT RNG GRAY MALE 20PK	44879	23876
08915-01	LOC EXT RANGE REPL MALE ORANGE	44879	23876
08915-20	LOC EXT RANGE REPL MALE ORANGE 20PK	44879	23876
09501-2	LOCATOR FIXED™ Insert, Four Unit (Green), (2 Pack)	44879	23876
09501-10	LOCATOR FIXED™ Insert, Four Unit (Green), (10 Pieces)	44879	23876
09506-2	LOCATOR FIXED™ Insert, Anterior / Posterior (Tan), (2 Pack)	44879	23876
09506-10	LOCATOR FIXED™ Insert, Anterior / Posterior (Tan), (10 Pieces)	44879	23876
09507-2	LOCATOR FIXED™ Insert, Mid Arch (Blue), (2 Pack)	44879	23876
09507-10	LOCATOR FIXED™ Insert, Mid Arch (Blue), (10 Pieces)	44879	23876
09508-4	LOCATOR Denture Attachment Housing Assembly, 4 pack	44879	23876
09508-10	LOCATOR Denture Attachment Housing Assembly, 10 pieces	44879	23876

Part Number	Description	GMDN Code	UMDNS Code
09509-01	LOCATOR Fixed Processing Package, Four Unit (Green)	44879	23876
09509-02	LOCATOR Fixed Processing Package, Anterior/Posterior (Tan)	44879	23876
09509-03	LOCATOR Fixed Processing Package, Mid Arch (Blue)	44879	23876