ZEST ANCHORS

ZD ZEST DENTAL SOLUTIONS™
ZEST | DANVILLE MATERIALS | PERIOSCOPY

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 Bar 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# 0086) Kitemark Court Davy Avenue, Knowlhill Milton Keynes, Mk5 8PP United Kingdom	BSI (NB# 2797) Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
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 10933-1:2009	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	August 27, 2019 Date

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Part Number	Description	GMDN Code	UMDNS Code
08028-2	LOCATOR Bar Male Processing Package (2 Pack), Final Pkg	44879	23876
08028-10	LOCATOR Bar Male Processing Package (10 Pack), Final Pkg	44879	23876
08586-2	LOCATOR Cast-To Bar Female (2 Pack), Final PKG	44879	23876
08586-10	LOCATOR, Cast-To Bar, Female, Assembly, 10 Pack, Final PKG	44879	23876
08587-2	LOCATOR Bar Female 2-56 Thread (2 pack), Final PKG	44879	23876
08587-10	LOCATOR Bar Female 2-56 Thread (10 pack), Final PKG	44879	23876
08588-2	LOCATOR Laser Bar Female Titanium (2 Pack), Final PKG	44879	23876
08588-10	LOCATOR Laser Bar Female Titanium (10 Pack), Final PKG	44879	23876
08589-2	LOCATOR Bar Female 2.0mm Thread '(2 Pack), Final Package	44879	23876
08589-10	LOCATOR Bar Female 2.0mm Thread (10 Pack), Final Package	44879	23876
08590-2	LOCATOR Laser Bar Female SS (2 Pack), Final PKG	44879	23876
08590-10	LOCATOR Laser Bar Female SS (10 Pack), Final PKG	44879	23876
08917-2	LOCATOR Abutment and Castable Collar for Multi-Unit (2 Pack), Final Package	44879	23876
08917-10	LOCATOR Abutment and Castable Collar for Multi-Unit (10 Pack), Final Package	44879	23876