ZEST ANCHORS

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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 F-Tx Fixed 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
	EN ISO 11137-1:2006	Sterilization of Health Care Products- Radiation Part 1: Requirements for Development, Validation, and Routine Control of a Sterilization Process for Medical Devices
	EN ISO 11137-2:2013	Sterilization of Health Care Products - Radiation - Part 2: Establishing the Sterilization Dose
	ASTM F1980:2007	Accelerated Aging
	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
	ISTA-6-FEDEX-A	FedEx Procedures for Testing Packaged Products Weighing Up to 150lbs.
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
10033-01	F-Tx Attachment System Low Retention Ball	44879	23876
10034-01	F-Tx Attachment System Medium Retention Ball	44879	23876
10035-01	F-Tx Attachment System High Retention Ball	44879	23876
10036-01	F-Tx Attachment System Healing Cap	44880	n/a
10041-01	F-Tx Attachment System Denture Attachment Housing	44879	23876