



EC DECLARATION OF CONFORMITY

We, Zest Anchors, LLC
2875 Loker Avenue East
Carlsbad, California 92010 U.S.A.

declare under sole responsibility that the LOCATOR® Implant Attachment System to which this declaration is related, meet the essential health and safety requirements as stated in Article 2 (Placing on the Market and Putting into Service) and are in conformity with Annex II EC Declaration of Conformity (Full Quality Assurance System) of the Council Directive 93/42/EEC concerning medical devices as amended by Directive 2007/47/EC and Statutory Instrument 2008 No. 2936.

The products noted below comply with Article 3 (Essential requirements), Annex I (Essential Requirements) (Section I) General Requirements and (Section II) Requirements Regarding Design and Construction and with all relevant provisions related to chemical, physical and biological properties, infection and microbial contamination, construction and environmental properties, electrical and thermal risks and information supplied by the manufacturer.

Zest Anchors, LLC has verified the mutual compatibility of the devices in accordance with the company's internal instructions and has carried out such operations in accordance with these instructions.

The LOCATOR® Implant Attachment System has been packaged and supplied with relevant information to users incorporating relevant instructions from the manufacturer. The whole activity is subjected to appropriate methods of internal control and inspection.

The LOCATOR® Implant Attachment System does not incorporate any of the following:

- medicinal substance
- non-viable materials of animal origin

Devices of Class IIa and IIb have been evaluated by a government accredited European third party organization, BSI Product Services per Annex II paragraph 5 (Surveillance).

The EU Authorized Representative, Wellkang Ltd trading as Wellkang Tech Consulting is located at 29 Harley St., W1G 9QR, LONDON, U.K.

The CE marking of conformity, as shown in Annex XII, must appear in a visible, legible and indelible form on the device, where practicable and appropriate, and on the Instructions for Use. The CE mark will be affixed on the devices according to Article 17 (CE marking) of the Council Directive 93/42/EEC. For devices of Class IIa and IIb, it shall be accompanied by the identification number of the Notified Body (0086) responsible for implementation of procedures set out in Annex II.

A handwritten signature in black ink, appearing to read 'Mark Stavro', is written over a horizontal line.

Mark Stavro
Director of Regulatory Affairs

A handwritten date 'July 23, 2018' in black ink is written over a horizontal line.

Date



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LOCATOR® Part Description	Zest Part Number	MIS Part Number	MDD Classification (per Annex IX, Section III)
Coni. con. Locator abutment 1mm hgt., NP	02143	CN-NZL01	IIb (Rule 8)
Coni. con. Locator abutment 2mm hgt, NP	02144	CN-NZL02	IIb (Rule 8)
Coni. con. Locator abutment 3mm hgt, NP	02145	CN-NZL03	IIb (Rule 8)
Coni. con. Locator abutment 4mm hgt, NP	02146	CN-NZL04	IIb (Rule 8)
Coni. con. Locator abutment 5mm hgt, NP	02147	CN-NZL05	IIb (Rule 8)
Coni. con. Locator abutment 1 mm hgt, SP	02149	CS-SZL01	IIb (Rule 8)
Coni. con. Locator abutment 2 mm hgt, SP	02150	CS-SZL02	IIb (Rule 8)
Coni. con. Locator abutment 3 mm hgt, SP	02151	CS-SZL03	IIb (Rule 8)
Coni. con. Locator abutment 4 mm hgt, SP	02152	CS-SZL04	IIb (Rule 8)
Coni. con. Locator abutment 5 mm hgt, SP	02153	CS-SZL05	IIb (Rule 8)
Locator abutment 0mm hgt, NP	02062	MB-NZL00	IIb (Rule 8)
Locator abutment 1mm hgt, NP	02063	MB-NZL01	IIb (Rule 8)
Locator abutment 2mm hgt, NP	02064	MB-NZL02	IIb (Rule 8)
Locator abutment 3mm hgt, NP	02065	MB-NZL03	IIb (Rule 8)
Locator abutment 4mm hgt, NP	02066	MB-NZL04	IIb (Rule 8)
Locator abutment 5mm hgt, NP	02067	MB-NZL05	IIb (Rule 8)
Locator abutment 6mm hgt, NP	02068	MB-NZL06	IIb (Rule 8)
Locator abutment 0mm hgt., standard platform	08661	MB-SZL00	IIb (Rule 8)
Locator abutment 1mm hgt., standard platform	08662	MB-SZL01	IIb (Rule 8)
Locator abutment 2mm hgt., standard platform	08663	MB-SZL02	IIb (Rule 8)
Locator abutment 3mm hgt., standard platform	08664	MB-SZL03	IIb (Rule 8)
Locator abutment 4mm hgt., standard platform	08665	MB-SZL04	IIb (Rule 8)
Locator abutment 5mm hgt., standard platform	08625	MB-SZL05	IIb (Rule 8)
Locator abutment 6mm hgt., standard platform	08626	MB-SZL06	IIb (Rule 8)
Locator abutment 0mm hgt., wide platform	08671	MB-WZL00	IIb (Rule 8)
Locator abutment 1mm hgt., wide platform	08672	MB-WZL01	IIb (Rule 8)
Locator abutment 2mm hgt., wide platform	08673	MB-WZL02	IIb (Rule 8)
Locator abutment 3mm hgt., wide platform	08674	MB-WZL03	IIb (Rule 8)
Locator abutment 4mm hgt., wide platform	08675	MB-WZL04	IIb (Rule 8)
Locator abutment 5mm hgt., wide platform	08627	MB-WZL05	IIb (Rule 8)
Locator abutment 6mm hgt., wide platform	08628	MB-WZL06	IIb (Rule 8)
Locator black processing replacement male (4 Pack)	08515	MM-LBP10	I
Locator core tool	08393	MM-LCT10	I
Locator extra light retention repl. male blue (4 Pack)	08529	MM-LEL10	IIa (Rule 5, third dash)
Locator extra light extended range male red (4 Pack)	08548	MM-LELE1	IIa (Rule 5, third dash)
Locator extended range replacement male green (4 Pack)	08547	MM-LER10	IIa (Rule 5, third dash)
Locator female analog (4mm diam.) (4 Pack)	08530	MM-LFA40	I
Locator female analog (5mm diam.) (4 Pack)	08516	MM-LFA50	I
Locator impression coping (4 Pack)	08505	MM-LIC10	I
Locator light retention replacement male pink (4 Pack)	08527	MM-LLR10	IIa (Rule 5, third dash)
Locator male processing package (2 Pack)	08519-2	MM-LMP02	IIa (Rule 5, third dash)
Locator male processing package (10 Pack)	08519-10	MM-LMP10	IIa (Rule 5, third dash)
Locator parallel post (4 Pack)	08517	MM-LPP10	I
Locator replacement male clear (4 Pack)	08524	MM-LRM10	IIa (Rule 5, third dash)