



TecnoSS[®] s.r.l.

Sede legale: Via Morghen 34 10100 Torino – Italy
Sede amministrativa: Piazza Papa Giovanni XXIII 2 10094 Giaveno (TO) – Italy
Stabilimento: Via Monte Nero 13 10050 Coazze (TO) – Italy
C.F. e P.I.: 07524260010
Registro Imprese del Tribunale di Torino n° 07524260010 Rea n° TO-902205
Capitale sociale: 40.000,00 Euro interamente versato

www.tecnoss.com
www.osteobiol.com
tecnoss@pec.it
info@tecnoss.com
Tel: +39 011 9377347
Fax: +39 011 9363262

DECLARATION OF CONFORMITY ACCORDING TO CE

TecnoSS s.r.l. warrants that the medical devices "OsteoBiol collagen and bone matrix", "OsteoBiol equine liophilized collagen felt" and "OsteoBiol membrane" are manufactured according to all applied essential qualifications as explained in Enclosure I of 93/42/EEC and 2007/47 EC directives

Therefore, TecnoSS s.r.l., under his responsibility

DECLARES

- That the above-mentioned medical devices satisfies the applied provisions of 93/42/EEC and 2007/47 EC directives
- That the above-mentioned medical devices belongs to class III
- That the above-mentioned devices is in conformity with the type described in CE certificate obtained in accordance to Enclosure III of 93/42/EEC and 2007/47 EC directives
- That the above-mentioned medical devices is CE marked according to the procedure explained in Enclosure V of 93/42/EEC and 2007/47 EC directives
- That the above-mentioned medical device is traded in STERILE packaging

Giaveno, 11/03/16

TECNOSS s.r.l.
Dr. Giuseppe Oliva



APPENDIX 1: DECLARATION OF CONFORMITY

We, Tecross s.r.l., hereby fully declare that the declaration of conformity of "OsteoBiol collagen and bone matrix", "OsteoBiol equine liophilized collagen felt" and "OsteoBiol membrane" medical devices, signed on 11/03/2016, refers to the following products:

Medical Device	Product name	Generic code	Size/Packaging	Product code
OSTEObIOL® BONE MATRIX LINE Sterile CE Certificate - Annex III - CTP 1146 16 CE Certificate - Annex V - QPZ 1334 11 Add 02-16	Gen-Os	MXXXXFY	0,25 gr 0,5 gr 1 gr 2 gr 1-2mm 1gr 2 gr	M1052FS M1052FE M1005FS M1005FE M1010FS M1010FE M1020FS M1020FE M0210FS M0220FS
	Apatos	AXXXXFY ASXXXXFY ACXXXXFY	Mix 0,5 gr Mix 1 gr Mix 2 gr Cortical 0,5 gr Cortical 1 gr Mix 1-2mm 1gr	A1005FS A1005FE A1010FS A1010FE A1020FS A1020FE AC1005FS AC1010FS A0210FS A0210FE
	mp3	A3XXXXFY	0,5 cc syringe 1 cc syringe 3x0,25 cc syringe 3x0,5 cc syringe 3x1.0 cc syringe 2 cc syringe 1-2mm 2 cc syringe	A3095FS A3095FE A3005FS A3005FE A3075FS A3015FS A3015FE A3030FS A3030FE A3010FS A3010FE A3210FS A3210FE
	Putty	HPTXXY	0,25cc syringe 0,5cc syringe 3x0,25 cc syringe 3x0,5 cc syringe 1cc syringe	HPT52S HPT09S HPT09E HPT32S HPT32E HPT35S HPT35E HPT61S HPT61E
	Gel	XXGELXXY	0,5cc syringe 3x0,5cc syringe	05GEL40S 05GEL40E 15GEL40S 15GEL40E
	Tablet	BLEXXY	2 blister of 10x10x10 mm	BLE21S BLE21E
	Sp-Block	BNXY	10 x 10 x 10mm 10 x 10 x 20mm 10 x 20 x 20mm 35 x 10 x 5mm	BN0E BN1E BN2E BN8E



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OSTEObIOL® BONE MATRIX LINE Sterile CE Certificate - Annex III - CTP 1146 16 CE Certificate - Annex V - QPZ 1334 11 Add 02-16	C-Block	CLNXY CLHXY	10 x 8 mm 5 x 5 mm 7 x 7 mm	CLN8S CLH5S CLH7S
	V-Block	CNXY	10 x 3 x 3 mm	CN0S
	Lamina	LSXXZY	25 x 25 x (0,4-0,6) Fine 25 x 35 x (0,4-0,6) Oval 20 x 40 x (0,4-0,6) Fine 30 x 30 x (2-4) Std 35 x 35 (0,8-1) Curved 35 x 35 (0,8-1) Semi-Soft 35 x 35 x (4-5) Norm	LS25FS LS25FE LS23FS LS23FE LS24LS LS03SS LS03SE LS10HS LS10HE LS35LS LS35LE LN35HE
	TSV Gel	TSVXXXY	0,5cc syringe 1cc syringe	TSV005S TSV005E TSV010S TSV010E
	Dual-Block	STNXY, STSXY	20x15x5mm soft curved 20x10x5mm norm curved	STS7S STN5S

Medical Device	Product name	Generic code	Size/Packaging	Product code
OSTEObIOL® EQUINE LIOPHILIZED COLLAGEN FELT, Sterile CE Certificate - Annex III - CTP 1147 16 CE Certificate - Annex V - QPZ 1334 11 Add 02-16	Duo-Teck	DTXXX	20 x 20 x (1.0) mm 20 x 20 x (0.1-0.5)	DT020 DTN625



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Medical Device	Product name	Generic code	Size/Packaging	Product code
OSTEOBIOL® DRIED MEMBRANES, Sterile CE Certificate - Annex III - CTP 1148 16 Addendum N°01-16 CE Certificate - Annex V - QPZ 1334 11 Add 02-16	Derma	EDXXZY	20 x 20 x (0,6) 12 x 8 x (0,8-1) mm 30 x 30 x (2-4) mm 25 x 25 x (0,8-1) mm 7 x 5 x (2.0) mm 15 x 5 x (2.0) mm 50 x 50 x (0,8-1) mm 50 x 50 x (2-4) mm	ED02LS ED21FS ED03SS ED25FS ED75SS ED15SS ED05FS ED05SS
	Special	EMXXZY	20x20mm 30x30mm	EM02LS EM02LE EM03LS EM03LE
	Condro-Teck	ADXZY/CR	5 x 5 mm 6 x 5 mm	AD5CS/CR AD6CS/CR
	Catila	ADXXZY/CR/SP	Ø 8 mm – hole 3 mm	AD83CE/CR
	Evolution X-Fine	EMXXZY	20x20mm 30x30mm	EM02XS EM03XS
	Evolution	EVXXLZE EVXXHZE EMXXZS EVOLZE EVOHZE	20x20mm Fine 20x20mm Std 30x30mm Fine 30x30mm Std Oval Fine (25x35mm) Oval Std (25x35mm) 40x40x(0.3-0.5)mm 80x60x(0.3-0.5)mm 20 x 20 x (0.2)mm 30 x 30 x (0.2)mm	EV02LLE EV02HHE EM02HS EV03LLE EV03HHE EM03HS EVOLLE EM00HS EV04LLE EV06LLE EM02XS EM03XS