

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
DynaFlex Instruments, Accessories	See Attached List	
MANUFACTURER		
Name of company	Address	Representative
DynaFlex	10403 International Plaza Drive St. Ann, MO 63074-1805	Matthew Malabey
AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com
REGISTRATION INFORMATION		
Notified Body and ID #	CE Certificate Number	Date CE Marking First Applied
		13 Jun 2013
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I Rule 5	Annex VII of MDD 93/42/EEC Council Directive	Reference Technical File

DynaFlex declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices and Directive 93/42/EEC as transposed in the national laws of the Member States.

COMPANY REPRESENTATIVE: Mr. Matthew Malabey

TITLE: Director Ops

SIGNATURE:



DATE: 03/22/2021



P.O. Box 99 • St. Ann, MO 63074-0099
Tel.: (314) 426.4020 • Fax: (314) 429.7575

List of Products and Models:

DynaFlex Part Number	Description
1050	DeImpactor Springs
1349	Retract-EEZ™ Cheek Retractor
1352	Mirahold Retractor
1353	Mirahold Retractor
1354	Photo Retractors
1355	Photo Retractors
1356-X	Disposable Extra-Oral Cheek Retractors
1363	NOLA DRY FIELD SYSTEM
1364	NOLA DRY FIELD SYSTEM
1416	Posterior Bracket Tweezer - Long Handle
1417	Posterior Bracket Tweezer - Small
1418	Bracket Tweezer
1443	Flush Cut Distal End Cutter
1450	Bendistal Plier Set
1602	Flush Cut Distal End Cutter
1605	POSITIONING BAND REMOVING PLIER
1607	Weingart Utility Plier
1607	Weingart Utility Plier
1611	BIRD BEAK PLIER
1615	Jarabak Plier
2022	Archwire Stops
4000	SALIVA EJECTORS
0795-14	PLATED PHOTOGRAPHIC MIRROR
1012-03	LIGHTENING STRIPS
1013-03	LIGHTENING STRIPS
1350-06	DOUBLE ENDED EXPANDER
1358-x	DISPOSABLE SPANDEEZ RETRACTOR
1400-014	HEMOSTAT



P.O. Box 99 • St. Ann, MO 63074-0099
Tel.: (314) 426.4020 • Fax: (314) 429.7575

1400-016	CURVED HEMOSTAT
1400-018	HOOKEED TIP HEMOSTAT
1400-025	Mathieu Forcep-Stainless Steel - Narrow
1400-025	Mathieu Forcep-Stainless Steel - Narrow
1417-15	Bracket Placement Instrument
1465-X	TRIMMING SCISSORS
1600-01	Small Distal End Cutter
1600-02	Long Handle Distal End Cutter
1603-01	SMALL PIN & LIGATURE CUTTER
1603-01	SMALL PIN & LIGATURE CUTTER
1604-05	STRAIGHT BRACKET REMOVER
1606-01	How Plier-Angulated
1632-03	STEP UP/DOWN PLIER
1632-03	STEP UP/DOWN PLIER
2022-W	Archwire Stop Wrench
4900-x	DISPOSABLE DENTAL MIRRORS
1350-05	Double Ended Expander
1350-06	Double Ended Expander
1373	DISPOSABLE MARKERS
1374	DISPOSABLE MARKERS
1400-030	Scaler/Band Pusher
1400-833	DynaFlex SS Hand Instrument
1429	Ligature Director
1480	Boley Gauge
1480-05	Micro Boley Gauge
1486	Round Plier Holder
1489	Plier Rack
1489-05	Plier Rack Cover
1491	Tie And Chain Organizer
1491-05	Dyna Stick Organizer
1493	Archwire Rack
1493-01	Archwire Rack
1494-01	Power Chain Rack
1494-20	Power Chain Organizer
0795-11	PLATED PHOTOGRAPHIC MIRROR
0795-13	PLATED PHOTOGRAPHIC MIRROR
0795-17	PLATED PHOTOGRAPHIC MIRROR
109-1336	Mini Stripper



P.O. Box 99 • St. Ann, MO 63074-0099
Tel.: (314) 426.4020 • Fax: (314) 429.7575

3011	Safety keys
3015	ACULIGHT LIGHTED SAFETY KEY
O-109-1055	TRIMMING WHEEL FOR ESSIX - 10M
O-109-1570	IPR GAUGE SET 6 SIZES
O-110-1004	SOFT-DEX RETRACTOR: CHILD (2)
O-110-1005	SOFT-DEX RETRACTOR: ADULT (2)
0714-011	DOME REPLACEMENT HEADS--7MM
0714-012	DOME REPLACEMENT HEADS--7MM
0714-014L	DOME REPLACEMENT HEADS--7MM
0716	DOME TOOTH STRIPPING HANDLE
0794-H	PHOTO HANDLE
0795-12	PLATED PHOTOGRAPHIC MIRROR
0795-15	PLATED PHOTOGRAPHIC MIRROR
O-100-1009	ORTHOCARE KIT
O-160-1002	ROTATION WEDGE CLEAR
O-222-2000	SELECT STRAIGHT PLIER RACK
O-110-1008	MIRAHOLD RETRACTOR: CHILD
O-110-1012	SPANDEX RETRACTOR: ADULT
1322	ZAND GAUGE KIT
O-152-1070	HABIT CONTROL DEVICE
1300	Bracket Wax
1309-CT	Scented Wax Boxes
1309-C	Scented Wax Boxes
1226	Elastic Attachers
1223	Elastic Attachers
0811-XX	CHAMPION COMFORT FIT FACEMASK
O-109-1331	MINI STRIP REFILL MICRO SAW ST
0778-01	INTERPROXIMAL HONEYCOMB DISC
O-108-1000	FIRST STEP PROPHY PASTE
O-109-1336	MINI STRIPPER KIT WITH 25 STRI
O-110-1028	SELECT DOUBLE ENDED RETRACTOR
O-600-1038	DISPOSABLE BONDING PAD
O-109-1302	DIAMOND DISC: DOUBLE SIDED
O-109-1333	MINI STRIP REFILL DS MEDIUM 4M
O-110-1055	E-Z RETRACTOR
O-109-1334	MINI STRIP REFILL SS MEDIUM 4M
O-110-1024	DOUBLE END RETRACTOR
0811-KEY	COMFORT FIT FACEMASK KEY ONLY
0811-R	FACEMASK REPLACEMENT PAD



P.O. Box 99 • St. Ann, MO 63074-0099
Tel.: (314) 426.4020 • Fax: (314) 429.7575

O-250-1048	HYGENIC UTILITY WAX STRIPS
O-110-1009	MIRAHOLD RETRACTOR: ADULT
O-600-1040	BONDING PAD ORGANIZER
0942	BRASS SEPARATING WIRE
1333	WIRE CHEEK RETRACTOR
O-110-1011	SPANDEX RETRACTOR: TEEN
O-160-1043	CRIMPABLE BALL HOOKS TOOTH COL
O-190-5050	ALUMINUM OXIDE: 50 MICRON 1LB
O-110-1058	LIP RING RETRACTOR: ADULT SET
O-190-5055	ALUMINUM OXIDE: 90 MICRON 1LB
1500	UNIVERSAL MODEL BASE FORMER
0761	DISC GUARD SET
0811-RNEW	VELCRO REPLACEMENT PAD
O-110-1010	SPANDEX RETRACTOR: CHILD
O-110-1022	DOUBLE END RETRACTOR
1336-C	MOUTHGUARDS
1430	BRACKET GAGUE
O-160-1037	SUPER SCREW WRENCH GREEN
1400-676	MOLAR BRACKET INSTRUMENT
1444	SELF LIGATING INSTRUMENT
1192	DISPOSABLE IMPRESSION TRAYS
143X	BRACKET HEIGHT GAUGE
1426-03	AUTOCLAVABLE BITE STICK
3823-500	CS Magnet
3823-SL	CS SL Tool
3823-EM	CS Allen Pencil Magnetic Type
1199-XX	SECURE LOCK IMPRESSION TRAYS
1400-024	SLIMLINE MATHIEU-SATIN FINISH
216-5000	Cool Tool Fork
216-5005	Cool Tool Pick
1458-H2	Crimpable Ball Hook Plier
0-190-1446	MINI DIGITAL CALIPER
0-109-1525	CONTACEZ THICKNESS GAUGE
4101-786	Molar Rotator Appliance 36mm
4101-787	Molar Rotator Appliance 38mm
1228-XX	Safe T Separators
0870-X	APPLIANCE REMOVER TOOL