



10403 International Plaza Dr. • St. Ann, MO 63074-0099
Tel.: (314) 426.4020 • Fax: (314) 429.7575

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
DynaFlex Archwires, Wires, & Springs	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
SIQ 1304	No. MDD-146	October 10, 2019
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Rule 5	Annex V 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: 07/10/2020



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List of Products and Models:

DynaFlex Part Number	Description
0900-xU	Stainless Steel Archwires Proform Round Upper
0900-xL	Stainless Steel Archwires Proform Round Lower
0902-xU	Stainless Steel Archwires Proform Rectangular Upper
0902-xL	Stainless Steel Archwires Proform Rectangular Lower
0910-xU	Dyna Ti Nickel Archwires Proform Round Upper
0910-xL	Dyna Ti Nickel Archwires Proform Round Lower
0911-xU	Dyna Ti Nickel Archwires Proform Rectangular Upper
0911-xL	Dyna Ti Nickel Archwires Proform Rectangular Lower
0919-xU	Hollywood Archwires Upper
0919-xL	Hollywood Archwires Lower
0920-xU	3-Strand Twist Archwire Proform Round Upper
0920-xL	3-Strand Twist Archwire Proform Round Lower
0922-xU	3-Strand Twist Archwire Proform Rectangular Upper
0922-xL	3-Strand Twist Archwire Proform Rectangular Lower
0924-xU	Stainless Steel Archwires Ultra-Form Round Upper
0924-xL	Stainless Steel Archwires Ultra-Form Round Lower
0925-xU	Stainless Steel Archwires Ultra-Form Rectangular Upper
0925-xL	Stainless Steel Archwires Ultra-Form Rectangular Lower
0927-xU	Dyna Ti Nickel Archwires Ultra-Form Round Upper
0927-xL	Dyna Ti Nickel Archwires Ultra-Form Round Lower
0928-xU	Dyna Ti Nickel Archwires Ultra-Form Rectangular Upper
0928-xL	Dyna Ti Nickel Archwires Ultra-Form Rectangular Lower
0931-xU	BioFlex3 Proform Upper
0931-xL	BioFlex3 Proform Lower
0932-xU	Dyna Ti – Reverse Curve II Nickel Titanium Archwires Round Upper
0932-xL	Dyna Ti – Reverse Curve II Nickel Titanium Archwires Round Lower
0933-xU	Dyna Ti – Reverse Curve II Nickel Titanium Archwires Rectangular Upper
0933-xL	Dyna Ti – Reverse Curve II Nickel Titanium Archwires Rectangular Lower
0934-xU	DynaFlex Dimple Nickel Titanium Round Upper
0934-xL	DynaFlex Dimple Nickel Titanium Round Lower
0935-xU	DynaFlex Dimple Nickel Titanium Rectangular Upper
0935-xL	DynaFlex Dimple Nickel Titanium Rectangular Lower
0936-xU	DynaFlex Dimple Reverse Curve – Type II Round Upper
0936-xL	DynaFlex Dimple Reverse Curve – Type II Round Lower
0937-xU	DynaFlex Dimple Reverse Curve – Type II Rectangular Upper
0937-xL	DynaFlex Dimple Reverse Curve – Type II Rectangular Lower



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0944-xU	DynaTherm Plus Proform Round Upper
0944-xL	DynaTherm Plus Proform Round Lower
0945-xU	DynaTherm Plus Proform Rectangular Upper
0945-xL	DynaTherm Plus Proform Rectangular Lower
0947-xU	DynaTherm Plus Ultra-Form Round Upper
0947-xL	DynaTherm Plus Ultra-Form Round Lower
0948-xU	DynaTherm Plus Ultra-Form Rectangular Upper
0948-xL	DynaTherm Plus Ultra-Form Rectangular Lower
0949-xU	DynaTherm Plus Opti-Form Round Universal
0950-xU	DynaTherm Plus Opti-Form Rectangular Universal
0950-x	14" Straight Round
0951-x	14" Straight Rectangular
0955-x	6-Strand Coaxial Archwire Standard Shape
0956-xU	8-Braid Archwire Standard Upper
0956-xL	8-Braid Archwire Standard Lower
0958-xU	6-Strand Coaxial Archwire Standard Proform Upper
0958-xL	6-Strand Coaxial Archwire Standard Proform Lower
0959-xU	8-Braid Archwire Proform Upper
0959-xL	8-Braid Archwire Proform Lower
0961-xU	CNA Archwire Proform Round Upper
0961-xL	CNA Archwire Proform Round Lower
0963-xU	CNA Archwire Proform Rectangular Upper
0963-xL	CNA Archwire Proform Rectangular Lower
0970-xL	DynaTorque Archwires 28mm Lower
0971-xU	DynaTorque Archwires 34mm Upper
0972-xU	DynaTorque Archwires 38mm Upper
0976-xU	Stainless Steel Archwires Opti-Form Round Upper
0977-xU	Stainless Steel Archwires Opti-Form Rectangular Upper
0980-xU	Dyna Ti Nickel Archwires Opti-Form Round Universal
0981-xU	Dyna Ti Nickel Archwires Opti-Form Rectangular Universal
0929-XX	NITI ARCHWIRE
0946-XX	DYNATHERM PLUS ARCHWIRE
9-033234	CNA REVERSE LOOP PALATAL ARCH
9-033236	CNA REVERSE LOOP PALATAL ARCH
09-XX-XX	COATED ARCHWIRE
09-XX	COPPER NITI
09-C27014	14 Copper Niti 27° Archwire
972	Nickel Titanium Distalizing Spring
975	Stainless Steel Ligature Long Ties 0.010
0975-001	Stainless Steel Ligature Short Ties 0.010



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0975-XX	Ligature ties
976	Stainless Steel Ligature Long Ties 0.012
0979-008	Spooled Ligature Wire 0.008
0979-010	Spooled Ligature Wire 0.010
0979-012	Spooled Ligature Wire 0.012
1000-010	Stainless Steel Kobayashi Long Ties 0.010
1000-012	Stainless Steel Kobayashi Long Ties 0.012
1000-014	Stainless Steel Kobayashi Long Ties 0.014
1001-012	Stainless Steel Kobayashi Short Ties 0.012
1001-014	Stainless Steel Kobayashi Short Ties 0.014
1002	Class II Type Springs
1003-GY	Grey Rotation Wedges
1003-C	Clear Rotation Wedges
1004-GY	DynaFlex Grey Rotation Wedges
1004-C	DynaFlex Clear Rotation Wedges
1007	Stainless Steel Closed Coil Spring
1007-101	Stainless Steel Open Coil Spring .009x028
1007-102	Stainless Steel Open Coil Spring .009x030
1007-103	Stainless Steel Open Coil Spring .009x036
1008-101	Stainless Steel Open Coil Spring .010x028
1008-102	Stainless Steel Open Coil Spring .010x030
1008-103	Stainless Steel Open Coil Spring .010x036
1009	FLAT LINGUAL RETAINER WIRE .010X.028
1010-H	Nickel Titanium Closing Spring 200 GMS 9mm
1010-M	Nickel Titanium Closing Spring 150 GMS 9mm
1010-L	Nickel Titanium Closing Spring 100 GMS 9mm
1011-1	Nickel Titantium Open Coil Spring 010x030
1011-2	Nickel Titantium Open Coil Spring 012x030
1011-3	Nickel Titantium Open Coil Spring 014x036
1011-4	Nickel Titantium Open Coil Spring 010x045
1011-5	Nickel Titantium Open Coil Spring 012x045
1012-L	Nickel Titanium Closing Spring 100 GMS 12mm
1018	NiTi Spool
1097	DynaFlex Shrink Tubing
1098	DynaFlex Super Soft Coil Spring Tubing
1100	Clear Elastic Thread 0.025
1100-030	Clear Elastic Thread 0.030
1101	Grey Elastic Thread 0.025
1101-030	Grey Elastic Thread 0.030
1102-GY	Grey Lip Bumper Tubing



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1102-C	Clear Lip Bumper Tubing
1105-018	Grey Elastic Sleeve 0.018
1105-027	Grey Elastic Sleeve 0.027
1106-018	Clear Elastic Sleeve 0.018
1106-027	Clear Elastic Sleeve 0.027
1108-025	Clear Ultra Tuff Thread 0.025
1108-030	Clear Ultra Tuff Thread 0.030
1109-025	Grey Ultra Tuff Thread 0.025
1109-030	Grey Ultra Tuff Thread 0.030
1458-H2	Crimpable Ball Hook Plier
2018	Crimpable Ball Hooks (20)
2018-5	Crimpable Ball Hooks (60)
2019	Crimpable Mini Stop Small 0.019
2021	Crimpable Mini Stop Large 0.030
2030	MIM Crimpable Stops
152-1050	Bite Builder
0975-XX	COLORED LIGATURE TIES
O-951-1200	NITI OPEN COIL SPRINGS
152-1070	Habit Control Device
1132	Ball Clasps
O-160-1027	SUPER SCREW WEXPANDER 16MM
O-160-1035	SUPER SCREW WEXPANDER 12MM W/WRENCH
09-SS-XXX	COATED ARCHWIRE
09-NXXX	COATED ARCHWIRE
1006-XX	COATED NITI OPEN COIL SPRING
1001-512	COATED KOBAYASHI TIES
O-160-1043	CRIMPABLE BALL HOOKS
O-160-1044	CRIMPABLE BALL HOOKS
GOLD	Wire Gold
O-952-8250	DEAD SOFT WIRE
38114	CS4 7mm Spring
38094	CS4 10mm Spring
3810-E	022 Traditional Pivot (Spring)
3810-SL	SL Pivot (Spring)
3815-5M	Hybrid Magnetic Type Screw (Spring)
3830-E	018 Traditional Pivot (Spring)
39-1807-10M	10-Patient Kit, 018 Pivots, 7mm Springs
39-1807-5M	5-Patient Kit, 018 Pivots, 7mm Springs
39-1810-10M	10-Patient Kit, 018 Pivots, 10mm Springs
39-1810-5M	5-Patient Kit, 018 Pivots, 10mm Springs
39-2207-10M	10-Patient Kit, 022 Pivots, 10mm Springs



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39-2207-5M	5-Patient Kit, 022 Pivots, 7mm Springs
39-2210-10M	10-Patient Kit, 022 Pivots, 10mm Springs
39-2210-5M	5-Patient Kit, 022 Pivots, 10mm Springs
39-SL07-10M	10-Patient Kit, SL Pivots, 7mm Springs
39-SL07-5M	5-Patient Kit, SL Pivots, 7mm Springs
39-SL10-10M	10-Patient Kit, SL Pivots, 10mm Springs
39-SL10-5M	5-Patient Kit, SL Pivots, 10mm Springs
39M-018	Master Kit, 018 System
39M-022	Master Kit, 022 System