

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
DynaFlex Elastomeric Products	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



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
1200-x	Extra-Oral Latex Elastics
1200-x	Rainforest Elastics Clear
1205-x	Rainforest Elastics Neon
1207-x	Rainforest Elastics Clear Non-latex
1208-x	Rainforest Elastics Neon Non-latex
1216-x	DynaStick Multicolor
1217-SC	DynaFlex Silicone Ties Super Clear
1217-SG	DynaFlex Silicone Ties Grey
1217-SS	DynaFlex Silicone Ties Silver
1233-x	DynaFlex Power Chain Continuous
1234-x	DynaFlex Power Chain Long
1235-x	DynaFlex Power Chain Short
1236-x	DynaFlex Mega Memory Chain Continuous
1237-x	DynaFlex Mega Memory Chain Long
1238-x	DynaFlex Mega Memory Chain Short
1240-x	Super Smooth Silicone Power Chain Continuous
1241-x	Super Smooth Silicone Power Chain Long
1242-x	Super Smooth Silicone Power Chain Short
0975-5x	COLORED LIGATURE TIES
1218-x	Single Sticks
1236-SI	Mega Memory Power Chain, Silver