

DEPCO, INC. 20 Newton Place, Hauppauge NY 11788-4752 USA

EU DECLARATION OF CONFORMITY

We at Depco Inc., located at 20 Newton Place, Hauppauge, New York 11788, USA, declare under sole responsibility that the product manufactured by us as:

Theraflex – Therapeutic Putty

This Medical Therapy device consists of silicone elastomer and produced in scaled hardness and color in individual quantities to be used for hand malady rehabilitation and exercise. Patients use the putty by squeezing and manipulating it in the hand during intervals according to treatments indicated by a therapist or a healthcare provider.

To which this declaration relates is in conformity with the essential requirements and provisions of Council Medical Device Directive 2007/47/EC as a Class 1 Therapeutic Medical Device, per Annex VII of Council Directive 93/42/EEC with Rule 1 of Annex IX and CE Medical Device Regulation (MDR) 2017/745/EC, referred to in Article 19, Annex VIII for classification and fulfils the specific obligations imposed by Article 52(7).

The general safety rules are met per Annex I and the clinical assessment rules are successfully evaluated, which included 40 years on the market, defining it as a Legacy device. The summary table below indicates applicable references:

Application of Council Directive	2007/47/EC Medical Device Directive 2017/745/EC Medical Device Regulation
Referenced standards or specifications	ASTM D-4326, ISO10993, GMP, ISO13485, 21CFR820, ISO14121, ISO14971, SVHC list
Manufacturers name	DEPCO, Inc.
Manufacturers address	20 Newton Place Hauppauge, NY 11788-4752 USA
Type of equipment	Therapeutic Silicone Elastomer Putty
Model No./UDI	Theraflex / 843509100 – See List page 2
Medical Device Classification	Risk Class 1 per Annex VIII MDR

The Authorized EU Representative Name and Address (SRN: BE-AR-000000661):  
MVS in Motion, Westdijk 150, BE-2830 Tisselt (Willebroek), Belgium

I, the undersigned, hereby declare that the equipment specified above conforms to the above directive(s).

*M. Gregory Minuto*

M. Gregory Minuto – C.E.O.  
Depco, Inc. USA

May 26, 2021

date

UDI-DI	Description
843509100006	Theraflex Putty Anti-Microbial 57g Extra Soft - Tan
843509100013	Theraflex Putty Anti-Microbial 57g Soft - Yellow
843509100020	Theraflex Putty Anti-Microbial 57g Medium - Red
843509100037	Theraflex Putty Anti-Microbial 57g Firm - Green
843509100044	Theraflex Putty Anti-Microbial 57g Extra Firm - Blue
843509100051	Theraflex Putty Anti-Microbial 85g Extra Soft - Tan
843509100068	Theraflex Putty Anti-Microbial 85g Soft - Yellow
843509100075	Theraflex Putty Anti-Microbial 85g Medium - Red
843509100082	Theraflex Putty Anti-Microbial 85g Firm - Green
843509100099	Theraflex Putty Anti-Microbial 85g Extra Firm - Blue
843509100105	Theraflex Putty Anti-Microbial 113g Extra Soft - Tan
843509100112	Theraflex Putty Anti-Microbial 113g Soft - Yellow
843509100129	Theraflex Putty Anti-Microbial 113g Medium - Red
843509100136	Theraflex Putty Anti-Microbial 113g Firm - Green
843509100143	Theraflex Putty Anti-Microbial 113g Extra Firm - Blue
843509100150	Theraflex Putty Anti-Microbial 170g Extra Soft - Tan
843509100167	Theraflex Putty Anti-Microbial 170g Soft - Yellow
843509100174	Theraflex Putty Anti-Microbial 170g Medium - Red
843509100181	Theraflex Putty Anti-Microbial 170g Firm - Green
843509100198	Theraflex Putty Anti-Microbial 170g Extra Firm - Blue
843509100204	Theraflex Putty Anti-Microbial 454g Extra Soft - Tan
843509100211	Theraflex Putty Anti-Microbial 454g Soft - Yellow
843509100228	Theraflex Putty Anti-Microbial 454g Medium - Red
843509100235	Theraflex Putty Anti-Microbial 454g Firm - Green
843509100242	Theraflex Putty Anti-Microbial 454g Extra Firm - Blue
843509100259	Theraflex Putty Anti-Microbial 2,3kg Extra Soft - Tan
843509100266	Theraflex Putty Anti-Microbial 2,3kg Soft - Yellow
843509100273	Theraflex Putty Anti-Microbial 2,3kg Medium - Red
843509100280	Theraflex Putty Anti-Microbial 2,3kg Firm - Green
843509100297	Theraflex Putty Anti-Microbial 2,3kg Extra Firm - Blue