EC Declaration of Conformity

Manufacturers Name:	Anatomy Supply Partners, LLC
Manufacturers Address:	7800 Third Flag Parkway, Austell, GA 30168 USA
SRN (Single Registration Number):	US-MF-000013500
Authorized Representative Name:	CEpartner4U
Authorized Representative Address:	Esdoornlaan 13, 3951 DB Maarn, The Netherlands
Basic UDI-DI:	0840216153094C
Name of the Device (s):	Squeeze Ball Hand Exerciser, 12/PK Rolyan Ergonomic Hand Exerciser, Black, Each Color-Coded Latex-Free Rubber Bands, Extra Light Color-Coded Latex-Free Rubber Bands, Light Color-Coded Latex-Free Rubber Bands, Medium Color-Coded Latex-Free Rubber Bands, Heavy Clips for Rolyan Basic Ergonomic Hand Exerciser Rolyan Basic Ergonomic Hand Exerciser, Black, Each Temper Foam R-Lite Foam Blocks, X-Soft 32/PK Temper Foam R-Lite Foam Blocks, Soft 32/PK Temper Foam R-Lite Foam Blocks, Medium 32/PK Temper Foam R-Lite Foam Blocks, Firm Temper Foam R-Lite Foam Blocks, All 12/PK
Intended Purpose:	Ball Hand Exercisers intended purpose is to strength the hand and wrist. Hand Exercisers intended purpose is to strength finger and forearm.
Product code:	GMDN 34200 Finger/Hand Exerciser
Risk Classification:	Class I, Rule 1 Noninvasive Devices
Conformity assessment route:	Anatomy Supply Partners, LLC uses the following procedures for the CE-labeling of their products according to Regulation MDR 2017/745: Class I: EC conformity declaration according to Annex II + Annex III.

This self-declaration of conformity is issued under the sole responsibility of Anatomy Supply Partners, LLC. We hereby declare that the medical device(s) specified above meet the provision of the Medical Device Regulations, MDR 2017/745. This declaration is supported by the Quality System compliance to ISO 13485.

All supporting documentation is retained at the premises of the manufacturer.

Signature:

Place and date (dd.mm.yyyy) of issue:

Sabrina Moore

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19.05.2023

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Sabrina Moore
Vice President of Quality & Regulatory Compliance

Finger/Hand Exerciser

Catalog number	Description
081033331	Squeeze Ball Hand Exerciser, 12/PK
A3481	Rolyan Ergonomic Hand Exerciser, Black, Each
A3482	Color-Coded Latex-Free Rubber Bands, Extra Light
A3483	Color-Coded Latex-Free Rubber Bands, Light
A3484	Color-Coded Latex-Free Rubber Bands, Medium
A3485	Color-Coded Latex-Free Rubber Bands, Heavy
A3486	Clips for Rolyan Basic Ergonomic Hand Exerciser
A3488	Rolyan Basic Ergonomic Hand Exerciser, Black, Each
081298231	Temper Foam R-Lite Foam Blocks, X-Soft 32/PK
081298306	Temper Foam R-Lite Foam Blocks, Soft 32/PK
081298314	Temper Foam R-Lite Foam Blocks, Medium 32/PK
081146968	Temper Foam R-Lite Foam Blocks, Firm
081298322	Temper Foam R-Lite Foam Blocks, All 12/PK

Harmonized Standards Used

Reference number	Description
BS EN ISO 14971:2019+A11:2021	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
BS EN ISO 20417:2021	Information supplied by the manufacturer of medical devices
IEC 62366-1:2015	Corrigendum 1 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices