



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): Jamar 9-Hole Pegboard, 9-Hole Pegboard
Two-Tiered Horizontal Bolt Board
25-Hole Pegboard with Colored Pegs
Jamar Grooved Peg Board, Jamar Grooved Pegboard
Jamar Manual Dexterity Test, Manual Dexterity Test
Jamar Tweezers Dexterity Test
Sammons Preston Graded Pegboard
Depth Perception Pegboard Set
Jamar 9-Hole Pegboard, Replacement Pegs
Jamar Finger Dexterity Test, Replacement Pins, 100
Jamar 9-Hole Peg Test Kit, Jamar 9-Hole Peg Test Kit
Jamar 9-Hole Peg Test Kit, Replacement Pegs, Nine
Jamar Pegboard Test, JAMAR Pegboard Test
Jamar Grooved Pegboard, 30 Replacement Pegs

Intended Purpose: Dexterity devices are intended to evaluate motor coordination, depth perception and eye-hand coordination

Product code: GMDN 63958 Manual Dexterity Test

Risk Classification: 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 the 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 Regulation (EU) MDR 2017/745 for medical devices. 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:

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10-12-2021.....

Sabrina Moore
Director of Quality & Regulatory
Compliance

Dexterity Test Devices

Catalog number	Description
5309	Jamar 9-Hole Pegboard, 9-Hole Pegboard
5328	25-Hole Pegboard with Colored Pegs
5329	Two-Tiered Horizontal Bolt Board
7446	Jamar Grooved Peg Board, Jamar Grooved Pegboard
7502	Jamar Manual Dexterity Test, Manual Dexterity Test
7521	Jamar Tweezers Dexterity Test
8180	Sammons Preston Graded Pegboard
8182	Depth Perception Pegboard Set
927037	Jamar 9-Hole Pegboard, Replacement Pegs
A8514	Jamar Finger Dexterity Test, Replacement Pins, 100
A8515	Jamar 9-Hole Peg Test Kit, Jamar 9-Hole Peg Test Kit
A8516	Jamar 9-Hole Peg Test Kit, Replacement Pegs, Nine
A9291	Jamar Pegboard Test, JAMAR Pegboard Test
A9685	Jamar Grooved Pegboard, 30 Replacement Pegs

Harmonized Standards Used

Reference number	Description
BS EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
BS EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN 1041:2008	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