



EC Declaration of Conformity

Manufacturers Name: Anatomy Supply Partners, LLC

Manufacturers Address: 7800 Third Flag Parkway, Austell, GA 30168 USA

SRN (Single Registration Number): [Insert number once AR registers ASP in EUDAMED]

Authorized Representative Name: CEpartner4U

Authorized Representative Address: Esdoornlaan 13, 3951 DB Maarn, The Netherlands

Basic UDI-DI: 08402161211001BH

Name of the Device (s): Jamar Dynamometers & Pinch Gauges

Intended Purpose: The Jamar Dynamometer & Pinch Gauge is intended for medical purposes to provide a measurement of the pinch and grip strength of a patient's hand. Measurements should be considered for reference purposes only.

Product Code: GMDN 35021 Dynamometer/pinch meter, mechanical

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:

A handwritten signature in cursive script that reads 'Sandra O'Reilly'.

Sandra O'Reilly
Director of Quality & Regulatory
Compliance

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

Austell GA 04 Aug 2021



Attachment to declaration of conformity Jamar Dynamometers & Pinch Gauges

Jamar Dynamometers & Pinch Gauges

Catalog number	Description
563213	Jamar Smart and Jamar Plus+ Hand Dynamometer, Jamar Plus+ Digital Hand Dynamometer
081028935	Jamar Hydraulic Hand Dynamometer, Jamar Hydraulic Hand Dynamometer
081028950	Jamar Hydraulic Hand Evaluation Kit
081187343	JAMAR Hydraulic Pinch Gauge
081504265	Jamar Digital Pinch Gauge
081505130	Jamar Plus+ Hand Evaluation Kit
081548545	Jamar Pinch Gauges, 0-45 lb. (0-20.4 kg)
081656842	JAMAR HAND EVALUATION KIT 2 WITH 30 LB PINCH GAUGE
081656859	JAMAR HAND EVALUATION KIT 2 WITH 45 LB PINCH GAUGE
081656867	JAMAR HAND EVALUATION KIT 2 WITH 60 LB PINCH GAUGE
081669928	Jamar Smart and Jamar Plus+ Hand Dynamometer, Jamar Smart Hand Dynamometer
A8531	Jamar Pinch Gauges, 0-30 lb. (0-13.6 kg)
A8532	Jamar Pinch Gauges, 0-60 lb. (0-27 kg)

Harmonized Standards

Reference number	Description
ANSI C63.4-2009	Methods of Measurement of Radio-Noise Emissions from Low-Voltage Electrical and Electronic Equipment in the Range of 9 kHz to 40 GHz
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
ETSI EN 300 328 V1.8.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques
ETSI EN 301 489-1 V1.9.2	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
ETSI EN 301 489-17 V2.2.1	Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
IEC 62366-1:2015	Corrigendum 1 - Medical Devices - Part 1: Application of Usability Engineering to Medical Devices