EU Declaration of Conformity

According to REGULATION (EU) 2017/745 of the European Parliament and of the Council

Manufacturer

Name Chinesport S.p.A.

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Single Registration Number SRN IT-MF-000005909

Product Information

Basic UDI-DI 8051881AROCP00015S

Product

Code	Name	Code	Name
AR10001	ERGO 10	AR10019	CLIPS AND BUTTONS
AR10002	ERGO 20	AR10020	LACES
AR10003	ERGO 100	AR10021	BUCKLES
AR10004	ERGO 400	AR10122	SET OF PINS
AR10005	CONNECTING SET	AR10124	SET OF KNOBS
AR10006	ERGO TABLE	AR10064	BASE FOR SCREWING
AR10007	TILT ERGO 1	AR10047	TRACKS SMALL BOARD
AR10025	ERGO 200	AR10048	TRACKS LARGE BOARD
AR10026	TILT ERGO 2	AR10049	ROLLING WHEEL
AR10008	HORIZONTAL SPIRAL	AR10051	BASKET
AR10009	VERTICAL SPIRAL	AR10052	HANGER
AR10010	OBLIQUE SPIRAL	AR10056	CLIMBY
AR10014	PRONO SUPINATION	AR10044	SMALL BASE WITH HOLES
AR10053	MAGIC SNAKE 1	AR10045	BIG BASE WITH HOLES
AR10054	MAGIC SNAKE 2	AR10141	FANTASY STICKS SET 6
AR10055	MAGIC SNAKE 3	AR10139	FANTASY STICKS SET 5
AR10011	WORM SCREW	AR10034	OLYMPIC DISCS SET 2
AR10012	FLEXO EXTENSION	AR100123	ELASTIC SLALOM
AR10050	LADDER 10 WITH HANDGRIP	AR100143	SPHERES SET ø20/ø40
AR10015	LATCHES	AR100135	MAGNETIC GAMES SET
AR10016	ELECTRICITY	AR10036	MAGNETIC GAMES SET 2
AR10017	HANDLES	AR10037	MAGNETIC GAMES SET 3

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Code	Name	Code	Name
AR10018	CUPS		

Intended Use	Devices for occupational therapy and ergotherapy, to improve motor and functional skills through active participation in daily activities.
Risk Class	I
Classification Rule	1
Common Specification [CS]	To date, there are no Common Specification available for this type of products in the Official Journal of the European Union

The manufacturer declares under its sole responsibility that the devices listed above comply with the essential safety and performance requirements of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning on medical devices (MDR).

Conformity Assessment Route

Compliance is assessed in accordance with Annex II and III by means of the applicable requirements of the following standards

EN 62366-1:2015+A1:2020	Medical devices Application of usability engineering to medical devices
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices. Symbols to be used with medical device labels, labeling and information to be supplied General requirements
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices
EN ISO 10993-1:2020	Biological evaluation of medical devices Evaluation and testing within a risk management process
EN 12182:2012	Assistive products for persons with disability - General requirements and test methods

Approval

Signature

Name	Mr. Angelo Snidero
Function	President and CEO
Place	Udine (Italy)
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