EU Declaration of Conformity

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

Manufacturer

Name	Chinesport S.p.A.
Registered Office	Via Croazia, 2 33100 - Udine (UD) ITALY +39 0432.621.621
Single Registration Number SRN	IT-MF-000005909

Product Information

Basic UDI-DI	8051881LMDRP0001AY
Product Name	THER DROP SWING - THER DROP
Product Code	**L** **M** * 1 1 * * X * **1** **2** 3 4 5 6 7 8 9 See product configuration table
Intended Use	Table for physical manipulation, massages, physiotherapy, chiropractic and osteopathy.
Risk Class	I
Classification Rule	1, 13
Accessories	There are no compatible accessories
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).

Product Configuration

This certificate is valid for all product configurations indicated in this table

L	**M**	*	*	*	*	*	*	*
1	**2**	3	4	5	6	7	8	9

POSITION	POSSIBLE VALUES	DESCRIPTION
1 - 2	LM	THER DROP LINE
3 - 4 - 5	111	THER DROP SWING
	211	THER DROP
6	A	HEAD SECTION WITH DROP
	B	MULTIFUNCTION HEAD SECTION WITH DROP
	C	HEAD SECTION WITHOUT DROP
7	1	CLASSIC SECTION WITH THORACIC DROP ONLY
	2	CLASSIC SECTION WITH LUMBAR DROP ONLY
	3	CLASSIC SECTIONS WITH THORACIC AND LUMBAR DROP
	4	FULL SECTION WITH THORACIC DROP ONLY
	5	FULL SECTION WITH LUMBAR DROP ONLY
	6	FULL SECTIONS WITH THORACIC AND LUMBAR DROP

EU Declaration of Conformity

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

POSITION	POSSIBLE VALUES	DESCRIPTION
	7	CLASSIC SECTION WITHOUT DROP
	8	FULL SECTION WITHOUT DROP
8	1	SINGLE SECTION WITH ONE DROP-PELVIC
	2	DIVIDED SECTION WITH 4 DROPS-PELVIC
	3	SECTION WITHOUT DROP-PELVIC
9	1	NO OPTION
10	X	SQUARED EDGES
11	A N 8 7 K S B 4 T 1 6 E Z G F H 9 Q R 2 3 L M P	UPHOLSTERY COLOURS

Conformity Assessment Route

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

EN 60601-1:2006 EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-1-2:2015	Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
EN 60601-2-52:2010+A1:2015	Medical electrical equipment Particular requirements for basic safety and essential performance of medical beds
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 62366-1:2015+A1:2020	Medical devices Application of usability engineering to medical devices

Approval

Signature

Name	Mr. Angelo Snidero
Function	President and CEO
Place	Udine (Italy)
Date of Issue	27/07/2023