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	8051881LVVST0001TN
Product Name	VISIT
Product Code	**L** **V** * * * * * * * **1** **2** 3 4 5 6 7 8 9 See product configuration table
Intended Use	Examination and treatments tables.
Risk Class	I
Classification Rule	1, 13
Accessories	See compatible accessories list
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	**V**	*	*	*	*	*	*	*
1	**2**	3	4	5	6	7	8	9

POSITION	POSSIBLE VALUES	DESCRIPTION
1 - 2	LV	VISIT LINE
3 - 4 - 5	111	VISIT 1 STANDARD
	112	VISIT 1 BASIC
	121	VISIT LARGE STANDARD
	122	VISIT LARGA BASIC
	131	VISIT EXTRA LARGE STANDARD
	132	VISIT ERTRA LARGE BASIC
	141	VISIT NAR STANDARD
	142	VISIT NAR BASIC
	151	VISIT TREND STANDARD
	152	VISIT TREND BASIC
	161	VISIT FLEXION STANDARD
	162	VISIT FLEXION BASIC

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POSITION	POSSIBLE VALUES	DESCRIPTION
	211	VISIT MOBIL STANDARD
	212	VISIT MOBIL BASIC
	221	VISIT MOBIL LARGE STANDARD
	222	VISIT MOBIL LARGE BASIC
6	A	ELECTRIC WITH FOOTSWITCH
	B	ELECTRIC WITH SIDEBAR
	C	HYDRAULIC
	D	ELECTRIC WITH HAND CONTROL
	G	ELECTRIC WITH FOOTSWITCH AND SUPPORT
	K	ELECTRIC WITH FOOTSWITCH
	N	ELECTRIC WITH SIDEBAR
	P	ELECTRIC WITH HAND CONTROL
	R	ELECTRIC WITH FOOTSWITCH AND SUPPORT
7	1	NO OPTIONS
	2	TRANSPORT WHEELS
	3	SAFETY SIDERAILS
	4	TRANSPORT WHEELS AND SAFETY SIDERAILS
	7	FOLDABLE SIDERAILS
8	W	SEAMLESS ROUNDED EDGES
	X	SQUARED EDGES
	Z	SEAMLESS ROUNDED EDGES AND HEATING SYSTEM
	Y	SQUARED EDGES AND HEATING SYSTEM
9	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

List of Compatible Accessories

This declaration is valid for the device used with the following accessories

CODE	DESCRIPTION
AC0037	ADDITIONAL FOOT PEDAL 1
AC0039	ADDITIONAL HAND CONTROL 1
AC0083	ADDITIONAL CONTROL 1
AC0997	FOOTSWITCH HOLDER
AC0578	SAFETY DEVICE
AC0017	AUXILIARY BATTERY
AC0031	PAPER ROLL HOLDER F
AC0699	PAPER ROLL HOLDER H
AC0032	PAPER ROLL HOLDER G
AC0034	STANDARD PAPER ROLL SET
AC0035	MAXI PAPER ROLL SET
AC0036	PROTECTIVE SHEET SET
AC0020.	BREATHING HOLE PLUG
AC0313	DRIP STAND SUPPORT
AC0027	DRIP STAND
AC1168	LUXURY BASE V KIT

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

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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, labelling 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	28/05/2021