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 8051881AVSTF0001DR

Product

A	**V**	**3**	*	*	*	*	*	*	*	*	*
1	**2**	**3**	4	5	6	7	8	9	10	11	12

Specific configurations

Product Code	Product Name
AV3221B3442C	STRUZZO 500
AV3521B3442C	STRUZZO 500 RC
AV3421B3442C	STRUZZO 500 RCR
AV3121A3452G	EASY-UP 100
AV3121B3452G	EASY-UP 200
AV3121A3454G	STAND-UP 100
AV3121A3454G	STAND-UP 200
AV3121A2454G	STAND-UP 300
AV3121A3554G	STAND-UP 400
AV3121A0113G	STAND-UP 500

See product configuration for the exhaustive list of variants

Intended Use	Configurable devices for lifting, maintaining a static upright position and assisted or autonomous transfer of patients.
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

A	**V**	**3**	*	*	*	*	*	*	*	*	*
1	**2**	**3**	4	5	6	7	8	9	10	11	12

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POSITION	POSSIBLE VALUES	DESCRIPTION
1 - 2 - 3	AV3	AV3 STANDING FRAME
4	1	STRUZZO
	2	STAND-UP / EASY UP
	4	STRUZZO PLUS
	5	STRUZZO RC
5	1	WODDEN FOOTPLATE
	2	METAL FOOTPLATES
6	1	ANATOMIC KNEE-SUPPORTS
	2	SOFT KNEE-SUPPORTS
7	A	AGJUSTMENT BY GAS SPRING
	B	ELECTRICAL ADJUSTMENT
8	0	MANUAL VERTICALIZATION
	2	GAS SPRING VERTICALIZATION
	3	ELECTRICAL VERTICALIZATION
9	3	SHORT SEAT
	4	LONG SEAT
10	4	SHORT ADJUSTABLE HANDLE
	5	LONG ADJUSTABLE HANDLE
11	2	DYNAMIC STRUCTURE
	3	FIXED STRUCTURE, FIXED HANDLES
	4	FIXED STRUCTURE, ADJUSTABLE HANDLES
12	B	SMALL PMMA SERVICE TRAY
	C	LARGE PMMA SERVICE TRAY
	F	SMALL POLYETHYLENE SERVICE TRAY
	G	LARGE POLYETHYLENE SERVICE TRAY

List of Compatible Accessories

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

CODE	DESCRIPTION	CODE	DESCRIPTION
AC0685	FIXED HEEL RESTS	AC1216	TRUNK SUPPORT
AC0686	ADJUSTABLE HEEL RESTS	01608	HAND ANCHOR
AC0689	COLORED PADDING	01609	HAND-WRIST GRIP
AC0691	ADJUSTABLE SHORT SEAT	AC1124	STORAGE BAG
AC0543	SHORT SEAT PADDING	AC0047	FOOT STRAP
AC0871	TOILET SEAT	AC0014	LEG STRAP
AC0690	ADJUSTABLE LONG SEAT	AC0783	BACK STRAP
AC0544	LONG SEAT PADDING	AC0782	LONG HANDLES
AC0048	POCKET FOR LONG SEAT	AC0703	ADJUSTABLE LATERAL / BACK SUPPORTS
AC0049	LATERAL SUPPORTS	AC0694	ANTI-CRUSHING FRONT SUPPORT
AC0702	ADJUSTABLE LATERAL SUPPORTS	AC0766	MEDIUM SERVICE TRAY
AC0014	LEG STRAP	AC0765	MEDIUM ABS TRAY
AC0783	BACK STRAP	AC1305	STRUZZO REMOTE CONTROL

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, 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)
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