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	8051881APELB0001W2
Product Name	ELBA - ISCHIA
Product Code	A P 1 0 0 0 3 X * (1 2 3 4 5 6 7 8 9) - A P 2 0 0 0 2 X * (1 2 3 4 5 6 7 8 9) See product configuration table
Intended Use	Transport chair intended for the transfer of patients in a hospital environement.
Risk Class	I
Classification Rule	1
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	P	*	0	0	0	*	X	*
1	2	3	4	5	6	7	8	9

POSITION	POSSIBLE VALUES	DESCRIPTION
1 - 2	AP	PATIENT TRANSFER CHAIR
3	1	ELBA
	2	ISCHIA
4 - 5 - 6	OOO	FIXED VALUES
7	2	MODEL 2
	3	MODEL 3
8	X	SQUARED EDGES
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

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List of Compatible Accessories

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

CODE	DESCRIPTION
AC0065	DRIP STAND
AC0066	CANISTER HOLDER
AC0067	SUPPORT HOOK
AC0063	SERVICE TRAY
AC0061	EXTRACTABLE LEG REST
AC0949.W	CERVICAL CUSHION

Conformity Assessment Route

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

EN 12182:2012	Assistive products for persons with disability - General requirements and test methods
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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