

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	8051881LDSHW0001BX																		
Product Name	SHOWER TROLLEY																		
Product Code	<table><tr><td>L</td><td>D</td><td>3</td><td>*</td><td>*</td><td>*</td><td>*</td><td>*</td><td>*</td></tr><tr><td>1</td><td>2</td><td>3</td><td>4</td><td>5</td><td>6</td><td>7</td><td>8</td><td>9</td></tr></table>	L	D	3	*	*	*	*	*	*	1	2	3	4	5	6	7	8	9
L	D	3	*	*	*	*	*	*											
1	2	3	4	5	6	7	8	9											
	See product configuration table																		
Intended Use	Shower trolleys for patient hygiene.																		
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	D	3	*	*	*	*	*	*
1	2	3	4	5	6	7	8	9

POSITION	POSSIBLE VALUES	DESCRIPTION
1 – 2 - 3	LD3	FIXED VALUES
4	1	PEDIATRIC USE
	2	ADULT USE
	3	BARIATRIC USE
5	C	HYDRAULIC PEDAL
	D	ELECTRIC WITH HAND CONTROL
	G	MULTIPURPOSE ERGONOMIC CONTROL
6	1	PATIENT PLATFORM 60 CM
	2	PATIENT PLATFORM 68 CM
	3	PATIENT PLATFORM 80 CM
7	1	PLATFORM LENGTH 188 CM
	2	PLATFORM LENGTH 203 CM
	3	PLATFORM LENGTH 218 CM

EU Declaration of Conformity

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



POSITION	POSSIBLE VALUES	DESCRIPTION
8	1	NON ADJUSTABLE BACKREST
	2	ADJUSTABLE BACKREST
9	1	WHEELS Ø 12.5CM
	2	WHEELS Ø 15CM

List of Compatible Accessories

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

CODE	DESCRIPTION
AC0039	HANDSET
AC0071	SPARE BATTERY
AC0083	ADDITIONAL MULTIPURPOSE CONTROL
AC0318	BATTERY CHARGER
AC0574	BACKREST EXTENSION
AC0575	SUPPORT FOR BUTTERFLY PEDAL
AC0578	SAFETY DEVICE
AC0838	IV POLE
AC0892	DRAIN KIT
AC1126	SHOWER MATTRESS STRAPS
AC1236	SOFT WEDGE CUSHION
AC1237	SOFT SEMI CYLINDRICAL CUSHION
SP0035	SOFT SHOWER MATTRESS – M
SP0041	SOFT SHOWER MATTRESS – S
SP0042	SOFT SHOWER MATTRESS – L

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

EU Declaration of Conformity

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



Approval

Signature

A handwritten signature in blue ink, appearing to read 'Angelo Snidero', is written over a faint, large, light-blue circular watermark.

Name

Mr. Angelo Snidero

Function

President and CEO

Place

Udine (Italy)

Date of Issue

02/08/2023