[EN] EU DECLARATION OF CONFORMITY
[IT] DICHIARAZIONE DI CONFORMITÀ UE
[ES] DECLARACIÓN UE DE CONFORMIDAD
[DE] EU-KONFORMITÄTSERKLÄRUNG
[FR] DÉCLARATION DE CONFORMITÉ UE

CHINESPORT ITALIA
REHABILITATION and MEDICAL EQUIPMENT

[EN] According to REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
[IT] In accordo con il REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO
[ES] De acuerdo con el REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO
[DE] Gemäß VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES
[FR] Conformément au RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL

CE

MANUFACTURER FABBRICANTE | PRODUCTOR | HERSTELLER |PRODUCTEUR	**REGISTERED OFFICE** SEDE LEGALE | OFICINA REGISTRADA | SIÈGE SOCIAL| REGISTRIERTES BÜRO	**SRN** NUMERO DI REGISTRAZIONE UNICO | NÚMERO DE REGISTRO ÚNICO | EINMALIGE REGISTRIERUNGSNUMMER | NUMÉRO D'ENREGISTREMENT UNIQUE
CHINESPORT SPA	Via Croazia, 2 33100 – Udine (ITALY)	-

[EN] This declaration of conformity UE is issued under the sole responsibility of the manufacturer
[IT] La presente dichiarazione di conformità UE è rilasciata sotto la responsabilità esclusiva del fabbricante.
[ES] Esta declaración de conformidad de la UE se emite bajo la responsabilidad exclusiva del fabricante.
[DE] Diese EU-Konformitätserklärung wird in der alleinigen Verantwortung des Herstellers ausgestellt
[FR] Cette déclaration de conformité UE est émise sous la seule responsabilité du fabricant

Basic UDI-DI UDI-DI BASE | UDI-DI BÁSICO | BASIS-UDI-DI |IUD-ID	8051881LVVST0001TN	**RISK CLASS** CLASSE DI RISCHIO | CLASE DE RIESGO | RISIKOKLASSE | CLASSE DE RISQUE	**I**
PRODUCT NAME NOME DEL PRODOTTO | NOMBRE DEL PRODUCTO | PRODUKTNAME | NOM DU PRODUIT	VISIT	**INSULATING CLASS(*)** CLASSE DI ISOLAMENTO | CLASE DE AISLAMIENTO | ISOLIERUNGSKLASSE| CLASSE D'ISOLATION	**II**
PRODUCT CODE CODICE DEL PRODOTTO | CÓDIGO DE PRODUCTO | PRODUKTCODE | CODE PRODUIT	L V * * * * * * *	**APPLIED PART** PARTI APPLICATE | PIEZAS APLICADAS | ANGEWANDTE TEILE | PIÈCES APPLIQUÉES	**B**

(*) electric models | versioni elettriche | versiones eléctricas | elektrische Versionen | versions électriques

[EN] **INTENDED USE**	[IT] DESTINAZIONE D'USO	[ES] USO PREVISTO	[DE] VERWENDUNGSZWECK	[FR] UTILISATION PRÉVUE
Examination and treatments tables	Lettini da visita e trattamento	Mesa de exploración y tratamiento	Untersuchungs- und Behandlungsliegen	Table d'examen et de traitement

COMMON SPECIFICATIONS [CS] SPECIFICHE COMUNI | ESPECIFICACIONES COMUNES | GEMEINSAME SPEZIFIKATIONEN| SPÉCIFICATIONS COMMUNES	-

[EN] We hereby declare that the devices listed above comply with the essential safety and performance requirements of REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRILE 2017 concerning medical devices (MDR).
[IT] Con la presente si dichiara che i dispositivi sopra elencati sono conformi ai requisiti essenziali si sicurezza e prestazione del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO E DEL CONSIGLIO DEL 5 APRILE 2017 relativo ai dispositivi medici (MDR).
[ES] Por la presente declaramos que los dispositivos enumerados anteriormente cumplen con los requisitos esenciales de seguridad y rendimiento del REGLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO Y DEL CONSEJO DE 5 DE ABRIL DE 2017 relativo a dispositivos médicos (MDR).
[DE] Hiermit erklären wir, dass die oben aufgeführten Geräte den grundlegenden Sicherheits- und Leistungsanforderungen der VERORDNUNG (EU) 2017/745 DES EUROPÄISCHEN PARLAMENTS UND DES RATES VOM 5. APRIL 2017 in Bezug auf Medizinprodukte (MDR) entsprechen.
[FR] Nous déclarons par la présente que les dispositifs énumérés ci-dessus sont conformes aux exigences essentielles de sécurité et de performance du RÈGLEMENT (UE) 2017/745 DU PARLEMENT EUROPÉEN ET DU CONSEIL DU 5 AVRIL 2017 relatif aux dispositifs médicaux (MDR)

[EN] This declaration is valid for the device used with the following accessories
[IT] La presente dichiarazione è valida per il prodotto usato con i seguenti accessori
[ES] Esta declaración es válida para el dispositivo utilizado con los siguientes accesorios
[DE] Diese Erklärung gilt für das Gerät, das mit folgendem Zubehör verwendet wird
[FR] Cette déclaration est valable pour l'appareil utilisé avec les accessoires suivants

COD.	DESCRIPTION	DESCRIZIONE
AC0037	ADDITIONAL FOOT PEDAL 1	PEDALIERA AGGIUNTIVA 1
AC0039	ADDITIONAL HAND CONTROL 1	PULSANTIERA AGGIUNTIVA 1
AC0083	ADDITIONAL CONTROL 1	COMANDO AGGIUNTIVO 1
AC0997	FOOTSWITCH HOLDER	SUPPORTO PER COMANDO
AC0578	SAFETY DEVICE	DISPOSITIVO DI SICUREZZA
AC0017	AUXILIARY BATTERY	BATTERIA AUSILIARIA
AC0031	PAPER ROLL HOLDER F	SUPPORTO LENZUOLINO F

AC0699	PAPER ROLL HOLDER H	SUPPORTO LENZUOLINO H
AC0032	PAPER ROLL HOLDER G	SUPPORTO LENZUOLINO G
AC0034	STANDARD PAPER ROLL SET	SET LENZUOLINO STANDARD
AC0035	MAXI PAPER ROLL SET	SET LENZUOLINO MAXI
AC0036	PROTECTIVE SHEET SET	SET TELINO DI PROTEZIONE
AC0020.	BREATHING HOLE PLUG	TAPPO FORO NASO/BOCCA
AC0313	DRIP STAND SUPPORT	SUPPORTI ASTA PORTAFLEBO
AC0027	DRIP STAND	PORTAFLEBO
AC1168	LUXURY BASE V KIT	KIT BASE LUXURY

PRODUCT CODE CONFIGURATION

CONFIGURAZIONE DEL PRODOTTO | CÓDIGO DE CONFIGURACIÓN DEL PRODUCTO | PRODUKTKONFIGURATIONSCODE | CODE DE CONFIGURATION DU PRODUIT /

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

Pos.	Values	Description	Descrizione
1 - 2	LV	VISIT LINE	VISIT LINE
3 - 4 - 5	111	VISIT 1 STANDARD	VISIT 1 STANDARD
	112	VISIT 1 BASIC	VISIT 1 BASIC
	121	VISIT LARGE STANDARD	VISIT LARGE STANDARD
	122	VISIT LARGA BASIC	VISIT LARGA BASIC
	131	VISIT EXTRA LARGE STANDARD	VISIT EXTRA LARGE STANDARD
	132	VISIT ERTRA LARGE BASIC	VISIT ERTRA LARGE BASIC
	141	VISIT NAR STANDARD	VISIT NAR STANDARD
	142	VISIT NAR BASIC	VISIT NAR BASIC
	151	VISIT TREND STANDARD	VISIT TREND STANDARD
	152	VISIT TREND BASIC	VISIT TREND BASIC
	161	VISIT FLEXION STANDARD	VISIT FLEXION STANDARD
	162	VISIT FLEXION BASIC	VISIT FLEXION BASIC
	211	VISIT MOBIL STANDARD	VISIT MOBIL STANDARD
	212	VISIT MOBIL BASIC	VISIT MOBIL BASIC
	221	VISIT MOBIL LARGE STANDARD	VISIT MOBIL LARGE STANDARD
	222	VISIT MOBIL LARGE BASIC	VISIT MOBIL LARGE BASIC
6	A	ELECTRIC WITH FOOTSWITCH	ELETTRICO CON PEDALIERA
	B	ELECTRIC WITH SIDEBAR	ELETTRICO CON BARRA PERIMETRALE
	C	HYDRAULIC	IDRAULICO
	D	ELECTRIC WITH HAND CONTROL	ELETTRICO CON PEDALIERA
	G	ELECTRIC WITH FOOTSWITCH AND SUPPORT	ELETTRICO CON BARRA PERIMETRALE
	K	ELECTRIC WITH FOOTSWITCH	ELETTRICO CON PEDALIERA
	N	ELECTRIC WITH SIDEBAR	ELETTRICO CON BARRA PERIMETRALE
	P	ELECTRIC WITH HAND CONTROL	ELETTRICO CON PEDALIERA
	R	ELECTRIC WITH FOOTSWITCH AND SUPPORT	ELETTRICO CON BARRA PERIMETRALE
7	1	NO OPTIONS	NESSUNA OPZIONE
	2	TRANSPORT WHEELS	RUOTE DI TRASFERIMENTO
	3	SAFETY SIDERAILS	SPONDINE DI SICUREZZA
	4	TRANSPORT WHEELS AND SAFETY SIDERAILS	RUOTE E SPONDINE
	7	FOLDABLE SIDERAILS	SPONDINE A SCOMPARSA
8	W	SEAMLESS ROUNDED EDGES	BORDI ARROTONDATI
	X	SQUARED EDGES	BORDI FASCIATI
	Z	SEAMLESS ROUNDED EDGES AND HEATING SYSTEM	BORDI ARROTONDATI CON RISCALDAMENTO
	Y	SQUARED EDGES AND HEATING SYSTEM	BORDI FASCIATI CON RISCALDAMENTO
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	COLOURS	COLORI

[EN] Compliance is assessed in accordance with Annex IX by means of the applicable parts of the following standards:

[IT] La conformità è valutata in accordo all'allegato IX mediante le parti applicabili delle seguenti norme:
[ES] El cumplimiento se evalúa de acuerdo con el anexo IX mediante las partes aplicables de las siguientes normas:
[DE] Die Einhaltung wird gemäß Anhang IX anhand der anwendbaren Teile der folgenden Normen bewertet:
[FR] La conformité est évaluée conformément à l'annexe IX au moyen des parties applicables des normes suivantes:

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 15223-1:2016	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

Udine (Italy), 2021.04.06
Mr. Angelo Snidero
(CEO)