[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)	**IT-MF-000005909**

[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	8051881LHTHR0001D5	**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	THER	**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 H * * * * * * *	**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
AC1169	LUXURY BASE T KIT	KIT BASE LUXURY
AC0018	LATERAL ARMRESTS	BRACCIOLI LATERALI
AC0021	RPG BAR FOR COUCH	ASTA RPG PER LETTINO
AC0022	WALL-MOUNTED BAR	ASTA RPG A PARETE

PRODUCT CODE CONFIGURATION

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

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

Pos.	Values	Description	Descrizione
1 - 2 - 3	LH1	THER LINE	THER LINE
4 - 5	81	THER 1 BASIC	THER 1 BASIC
	11	THER 1	THER 1
	71	THER 1 LUX	THER 1 LUX
	21	THER PLUS 1	THER PLUS 1
	51	THER PLUS 1 LUX	THER PLUS 1 LUX
	82	THER 2 BASIC	THER 2 BASIC
	12	THER 2	THER 2
	72	THER 2 LUX	THER 2 LUX
	22	THER PLUS 2	THER PLUS 2
	52	THER PLUS 2 LUX	THER PLUS 2 LUX
	83	THER NAR BASIC	THER NAR BASIC
	13	THER NAR	THER NAR
	73	THER NAR LUX	THER NAR LUX
	23	THER PLUS NAR	THER PLUS NAR
	53	THER PLUS NAR LUX	THER PLUS NAR LUX
	84	THER FLEXION BASIC	THER FLEXION BASIC
	14	THER FLEXION	THER FLEXION
	74	THER FLEXION LUX	THER FLEXION LUX
	24	THER PLUS FLEXION	THER PLUS FLEXION
	54	THER PLUS FLEXION LUX	THER PLUS FLEXION LUX
	87	THER MODULAR BASIC	THER MODULAR BASIC
	17	THER MODULAR	THER MODULAR
	77	THER MODULAR LUX	THER MODULAR LUX
	27	THER PLUS MODULAR	THER PLUS MODULAR
	57	THER PLUS MODULAR LUX	THER PLUS MODULAR LUX
	88	THER GYN BASIC	THER GYN BASIC
	18	THER GYN	THER GYN
	26	THER PLUS GLOBAL	THER PLUS GLOBAL
	56	THER PLUS GLOBAL LUX	THER PLUS GLOBAL LUX
	09	THER OSTEO D	THER OSTEO D
	35	THER OSTEO	THER OSTEO
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
8	W	SEAMLESS ROUNDED EDGES	BORDI ARROTONDATI
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), 2021.05.28
Mr. Angelo Snidero
(CEO)