

[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



MANUFACTURER

FABBRICANTE | PRODUCTOR | HERSTELLER | PRODUCTEUR

CHINESPORT SPA

REGISTERED OFFICE

SEDE LEGALE | OFICINA REGISTRADA | SIÈGE SOCIAL |
REGISTRIERTES BÜRO

Via Croazia, 2
33100 – Udine (ITALY)

SRN

NUMERO DI REGISTRAZIONE UNICO | NÚMERO DE REGISTRO ÚNICO |
EINMALIGE REGISTRIERUNGSNUMMER | NUMÉRO
D'ENREGISTREMENT UNIQUE

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

8051881LMDRP0001AY

PRODUCT NAME

NOME DEL PRODOTTO | NOMBRE DEL PRODUCTO |
PRODUKTNAMEN | NOM DU PRODUIT

THER DROP

PRODUCT CODE

CODICE DEL PRODOTTO | CÓDIGO DE PRODUCTO |
PRODUKTCODE | CODE PRODUIT

L M * 1 1 * * * * X *

RISK CLASS

CLASSE DI RISCHIO | CLASE DE RIESGO | RISIKOKLASSE |
CLASSE DE RISQUE

RULE

REGOLA | REGLA | REGEL | RÈGLE

INSULATING CLASS

CLASSE DI ISOLAMENTO | CLASE DE AISLAMIENTO |
ISOLIERUNGSKLASSE | CLASSE D'ISOLATION

APPLIED PART

PARTI APPLICATE | PIEZAS APLICADAS | ANGEWANDTE TEILE |
PIÈCES APPLIQUÉES

I

13

II

B

[EN]

INTENDED USE

Physical manipulation,
massage, physiotherapy,
chiropractic and osteopathy
table.

[IT]

DESTINAZIONE D'USO

Letto per manipolazione
fisica, massaggi, fisioterapia,
chiropratica ed osteopatia.

[ES]

USO PREVISTO

Mesa de manipulación
física, masajes,
fisioterapia, quiropráctica
y osteopatía.

[DE]

VERWENDUNGSZWECK

Liege für Manipulation,
Massage, Physiotherapie,
Chiropraktik und
Osteopathie

[FR]

UTILISATION PRÉVUE

Table de manipulation
physique, massage,
physiothérapie, chiropratique
et ostéopathie.

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 APRIL 2017 concerning medical devices (MDR).

[IT] Con la presente si dichiara che i dispositivi sopra elencati sono conformi ai requisiti essenziali di 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)

PRODUCT CODE CONFIGURATION

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

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

Pos.	Values	Description	Descrizione
1 - 2	LM	THER DROP LINE	THER DROP LINE
3 - 4 - 5	111	THER DROP SWING	THER DROP PRO
	211	THER DROP	THER DROP
6	A	HEAD SECTION WITH DROP	TESTATA CON DROP
	B	MULTIFUNCTION HEAD SECTION WITH DROP	TESTATA MULTIFUNZIONE CON DROP
	C	HEAD SECTION WITHOUT DROP	TESTA SENZA DROP
7	1	CLASSIC SECTION WITH THORACIC DROP ONLY	DROP TORACICO CLASSICO
	2	CLASSIC SECTION WITH LUMBAR DROP ONLY	DROP LOMBARE CLASSICO
	3	CLASSIC SECTIONS WITH THORACIC AND LUMBAR DROP	DROP TORACICO E LOMBARE CLASSICO
	4	FULL SECTION WITH THORACIC DROP ONLY	DROP TORACICO OSTEO
	5	FULL SECTION WITH LUMBAR DROP ONLY	DROP LOMBARE OSTEO
	6	FULL SECTIONS WITH THORACIC AND LUMBAR DROP	DROP TORACICO E LOMBARE OSTEO
	7	CLASSIC SECTION WITHOUT DROP	SENZA DROP
	8	FULL SECTION WITHOUT DROP	SENZA DROP OSTEO
8	1	SINGLE SECTION WITH ONE DROP-PELVIC	DROP PELVICO SINGOLO

	2	DIVIDED SECTION WITH 4 DROPS-PELVIC	4-DROP PELVICI
	3	SECTION WITHOUT DROP-PELVIC	SENZA DROP PELVICO
9	1	NO OPTION	NESSUNA OPZIONE
10	X	SQUARED EDGES	BORDI FASCIATI
11	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 II and III by means of the applicable parts of the following standards:

[IT] La conformità è valutata in accordo all'allegato II e III mediante le parti applicabili delle seguenti norme:

[ES] El cumplimiento se evalúa de acuerdo con el anexo II y III mediante las partes aplicables de las siguientes normas:

[DE] Die Einhaltung wird gemäß Anhang II und III anhand der anwendbaren Teile der folgenden Normen bewertet:

[FR] La conformité est évaluée conformément à l'annexe II et III au moyen des parties applicables des normes suivantes:

EN 60601-1:2006 EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 EN 60601-1-6:2010+A1:2015	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 60601-2-52:2010+A1:2015	Medical electrical equipment General requirements for basic safety and essential performance. Collateral Standard: Electromagnetic disturbances. Requirements and tests
EN ISO 14971:2019	Medical electrical equipment Particular requirements for basic safety and essential performance of medical beds
EN ISO 15223-1:2021	Medical devices - Application of risk management to medical devices
EN ISO 1041:2008+A1:2013	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements
EN ISO 10993-1:2020	Information supplied by the manufacturer of medical devices
EN 62366-1:2015+A1:2020	Biological evaluation of medical devices Evaluation and testing within a risk management process
	Medical devices Application of usability engineering to medical devices

Udine (Italy), 2023.03.01

Mr. Angelo Snidero
(CEO)