DAVIS

Traction/immobilization system

Davis traction systems are devices that limit tissue damage caused by possible bone rubbing by spacing the two halves of a fracture.

Specific features
Sturdy and lightweight structure
4 padded supports offer greater comfort and a better weight distribution
Elastic immobilization bands
Padded and adjustable ankle band
Soft ischial padding increase leg stability and patient comfort
Transport bag with pocket and strap closure allows easy storage of the device and accessories

Technical data	
Minimum length[(1)]	890 ± 10 mm
Maximum length[(1)]	1350 ± 10 mm
Width	210 mm
Base width	230 mm
Width of leg support area	165 mm
Traction belt length	From 0 to 500 mm
Inclination	10° (variable depending on the extension)
Materials	Steel, Al, Nylon
Weight	1.78 ± 0.1 kg
Bag dimensions	990 x 330 mm
Bag weight	520 g

[(1)] The limb must be approximately 15 cm shorter than the indicated measurements

Sizes subject to ± 10 mm tolerances

Standard equipment
Transport bag

Class I MD compliant with UE Reg. 2017/745	
DAVIS ADULT TRACTION SYSTEM	CE
SR01010A	
CND Classification	V9099
Registration number	195373

Nato stock N° 6515-15-119-2408

Digitally signed by Gorgan Vasile-Dan
Date: 2023.05.15 18:22:32 EEST
Reason: MoldSign Signature
Location: Moldova

Spencer Italia S.r.l. Sala Baganza (PR) Italia Tel. +39.0521.541111 Fax +39.0521.541222
www.spencer.it

EU DECLARATION OF CONFORMITY/ *DICHIARAZIONE DI CONFORMITA' UE*

Regulation/Regolamento UE 2017/745

The declaration is released under the sole responsibility of the manufacturer
La dichiarazione è rilasciata sotto la responsabilità esclusiva del fabbricante

Manufacturer/*Fabbricante:*	**Spencer Italia s.r.l.** Via Provinciale, 12 – 43038 Sala Baganza (PR) – Italy
Unique registration number/ *Numero di registrazione unico:*	Eudamed is not active/ *Banca Eudamed non attiva*
Medical Device/*Dispositivo Medico:*	DAVIS ADULT TRACTION SYSTEM/ *DAVIS SISTEMA DI TRAZIONE ADULTO*
Code /*Codice:*	SR01010A
BASIC UDI-DI /*UDI-DI di base:*	805771123SISTEMATRAZKU
Lot/ *Lotto* SN/ *Matricola*	Not available before the production/ *Non disponibile prima della produzione*
Quantity/*Quantità:*	1
Risk class /*Classe di rischio:* (Annex VIII/*Allegato VII)*	I
Conformity assessment procedure/ *Procedura valutazione conformità*	Not present /*Non presente*
Rule/*Regola:*	1

Spencer Italia S.r.l. declares under its sole responsibility that the above mentioned medical device is in compliance with the requirements of the Regulation 2017/745 and with the applicable regulations and common specifications.
Spencer Italia S.r.l. *dichiara sotto la sua sola responsabilità che il Dispositivo Medico sopra menzionato, è conforme ai requisiti del Regolamento 2017/745, alle norme e alle specifiche comuni applicabili.*

The list of applicable standards is reported in the Technical File.
La lista delle norme applicabili è riportata nel relativo Fascicolo Tecnico.

Sala Baganza (PR) - IT, 03/04/2022

First name and surname /*Nome e cognome:*_____

Role/*Ruolo:* _____ Signature/*Firma:*_____

Person in whose name and on whose behalf this declaration of conformity has been signed/
Persona a nome e per conto della quale è stata firmata la presente Dichiarazione UE :

Antonio Ciardella
(Legal Representative /*Legale Rappresentante)*

Italia

CERTIFICATO

Nr. 50 100 6189 Rev.006

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

Spencer Italia s.r.l.

SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:

VIA PROVINCIALE 12
IT - 43038 SALA BAGANZA (PR)

SEDI OPERATIVE: **VEDI ALLEGATO 1** / *OPERATIONAL SITES:* ***SEE ANNEX 1***

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non (IAF 19, 14, 29)

Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands (IAF 19, 14, 29)

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2021-08-05**

Al / To: **2024-08-04**

Data emissione / *Issuing Date*

2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 6189 Rev.006**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 6189 Rev.006***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 6189 Rev.006 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 6189 Rev.006 COVERS ALSO THE FOLLOWING OFFICES:*

Spencer Italia s.r.l.

VIA PROVINCIALE 12 **IT - 43038 SALA BAGANZA (PR)**	Progettazione, sviluppo e produzione di dispositivi per l'emergenza e funerario. Commercializzazione di prodotti per il settore medicale, emergenza, soccorso e funerario a marchio proprio e non *Design, development and production of emergency and mortuary equipment. Distribution of medical, emergency rescue and mortuary equipment with own and other brands*
VIA PETITOT 4 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*
VIA LEGA DEI CARRETTIERI 3 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing and Distribution of medical, emergency and rescue equipment with own and other brands*
VIA PROVINCIALE 38 **IT - 43038 SALA BAGANZA (PR)**	Immagazzinamento di prodotti per il settore medicale, emergenza e soccorso a marchio proprio e non *Warehousing of medical, emergency and rescue equipment with own and other brands*

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità /*Validity*
Dal / From: **2021-08-05**
Al / To: **2024-08-04**

Andrea Coscia
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione / *Issuing Date*
2021-08-05

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2006-10-03

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE 2021-08-04
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2021-08-04*

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 033230 0033 Rev. 00

Holder of Certificate: **Spencer Italia s.r.l.**
Via Provinciale 12
43038 Sala Baganza (PR)
ITALY

Certification Mark:

Scope of Certificate: **Design and development, production of emergency equipment; Distribution of medical, emergency and rescue equipment with own and other brands**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 033230 0033 Rev. 00

Report No.: ITA 1683049

Valid from: 2021-11-09
Valid until: 2024-08-04

Date, 2021-11-09

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 033230 0033 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

Spencer Italia s.r.l.
Via Provinciale 38, 43038 Sala Baganza (PR), ITALY

\Warehousing of medical, emergency and rescue equipment with own and other brands.

Spencer Italia s.r.l.
Via Provinciale 12, 43038 Sala Baganza (PR), ITALY

Design and development,, production of emergency equipment; Distribution of medical, emergency and rescue equipment with own and other brands

Spencer Italia s.r.l.
Via Petitot 4, 43038 Sala Baganza (PR), ITALY

Warehousing of medical, emergency and rescue equipment with own and other brands.

Spencer Italia srl
Via Lega dei Carrettieri 3, 43038 Sala Baganza (PR), ITALY

Warehousing and Distribution of medical, emergency and rescue equipment with own and other brands.

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