

# I.V. House, Inc.

## Capabilities Statement

### Corporate Data

I.V. House is the world leader in the design and development of innovative products that stabilize, secure, and protect IV insertion sites. Hospitals worldwide use these devices to prevent patient harm and reduce costs associated with those injuries. I.V. House products combine Human Factors and Ergonomics with thoughtful input from nurses to deliver real-world solutions that improve patient safety and increase nurse efficiency. I.V. House is a certified Woman-Owned Business Enterprise (WBE) through the State of Missouri, Office of Administration, and qualifies as a small business as defined by the U.S. Small Business Administration under the category 339112, Surgical and Medical Instrument Manufacturers.

### Quality Assurance

All I.V. House products are made in the USA with raw materials sourced from U.S. companies. All products are created to adhere to best practices in manufacturing and the I.V. House Quality Management System. I.V. House products are assembled and packaged at facilities that employ adults with disabilities or those with other barriers to employment.

### Award-Winning Design

I.V. House, Inc. has earned six awards in the medical technology arena: The TLC Splint won a 2019 Silver Edison Award for innovation, and two Good Design Awards (2019 and 2015), given by The Chicago Athenaeum Museum of Architecture and Design. The I.V. House UltraDressing won three awards including the prestigious Medical and Scientific Equipment Gold IDEA winner (Industrial Design Excellence Award), presented by the Industrial Designers Society of America and sponsored by Business Week Magazine.

### International Registrations

**Australia:** Australian Government Department of Health, Therapeutic Goods Administration

**Italy:** Ministry of Health (Ministero della Salute)

**Philippines:** Department of Health, Food and Drug Administration, Center for Device Regulation, Radiation Health and Research

**Republic of Korea:** Ministry of Food and Drug Safety

**Saudi Arabia:** Saudi Food & Drug Authority, Medical Devices National



Wellkang LTD, Enterprise Hub,  
NW Business Complex, 1 Beraghmore Rd,  
Derry, BT48 8SE, Northern Ireland

DUNS: 805602950  
CAGE: 1QMP3  
NAICS: 339112

### FDA Information

Owner/Operator No: 9044986  
510(K) No: K912942

### Contract/Agreement

DAPA: SP0200-16-H-0010

### Contact Information

I.V. House, Inc.  
2072 Concourse Dr.  
St. Louis, MO 63146  
Phone: (314) 453-9200  
Toll Free: (800) 530-0400  
Fax: (314) 453-9576  
orders@ivhouse.com  
IVInfo@ivhouse.com

### Authorized Distributors

Cardinal Health, Inc.  
The Claflin Company  
Concordance Healthcare Solutions  
Medline Industries, Inc.  
Owens & Minor

### ISO Certified

I.V. House, Inc. is an ISO 13485:2016 registered company in respect to the Manufacture and Distribution of Peripheral IV Site Protection and Joint Stabilization Devices. PJR Certificate no. C2023-04201

### HS Codes

International Codes: 9018.9080

### EudaMed

EudaMed SRN Number Current Actor:  
Manufacturer, US-MF000021932, I.V. House, Inc. [United States]

### MHRA

MHRA Ref. Number: 24076

### GMDN Codes

#### TLC Splints

GMDN Code: 61139  
GMDN Term Name: Arm procedure positioner, single-use

#### I.V. House UltraDomes and UltraDressings

GMDN Code: 65042  
GMDN Term Name: Intravenous access site protector



**I.V. HOUSE**<sup>®</sup>  
Protection Over and Above<sup>®</sup>

REV 2023-08-31

I.V. House, Inc. / St. Louis, MO 63146 USA

314-453-9200 / 800-530-0400 / FAX 314-453-9576 / IVInfo@ivhouse.com / www.ivhouse.com