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 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, Medial Devices National



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

ISO 13485 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

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

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 posi-

tioner, single-use

I.V. House UltraDomes and UltraDressings

GMDN Code: 65042

GMDN Term Name: Intravenous access

site protector