stryker

EU Declaration of Conformity TO MEDICAL DEVICE REGULATION 2017/745			
Manufacturer (Name, Address, SRN)	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA SRN: US-MF-000000542		
EU Authorized Representative Name, Address	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co Cork, T45 HX08 Ireland		
Declaration of Conformity Document Number	DOC-61	**Revision Number**	B

See Appendix A for Device information

We hereby declare under our sole responsibility of the manufacturer that these products conform with the relevant provisions of the Medical Device Regulation (EU) 2017/745.

We hereby declare under our sole responsibility of the manufacturer that the products conform to the harmonized standard EN IEC 63000, and thereby comply with the Directive (EU) 2011/65/EU (RoHS2), as amended, including commission delegated Directive (EU) 2015/863 (RoHS3).

We hereby declare under our sole responsibility of the manufacturer that the products indicated with "*" on the product list conform to the Radio Equipment Directive 2014/53/EU. The products are in conformity with the following standards and/or documents.

- EN 60601-1:2006+A1:2013
- EN 60601-1-2:2015
- ETSI EN 300 330 V2.1.1

We declare, under our sole responsibility, that the products specified in the product list also conform to the following regulations and directives: (Write N/A where applicable)	Machinery Directive (2006-42-EC)

Name and Number of Notified Body [1]	**Conformity Assessment Procedure**	**Certificate Number [1]**
N/A	This device conforms to the requirements of Annex II and Annex III of Regulation (EU) 2017/745.	N/A

[1] This section is N/A for Class I (self-certified) devices.

Reference to Common Specifications (Write N/A when not applicable)	N/A
Additional Information (Write N/A when not applicable)	N/A

Person Responsible for Regulatory Compliance or Designee Name and Function	Melissa Lalomia, Senior Director Regulatory Affairs & Clinical Sciences
Place and Date of Issue (1)	Portage, MI (1) Effective Date: July 12, 2021
Signature	Melissa Lalomia

Appendix A:

Main Devices:

Product Number	Product Name	Basic UDI-DI	Risk Class	Rule	Measuring Function (Y/N)	Intended Purpose	Manufactured by
6506-000-000*	Power-PRO™ XT	08858250000295S2	I	13	N	A	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	Rule	Measuring Function (Y/N)	Intended Purpose	Manufactured by
6500-310-000	Havasu™	08858250000303R8	I	1	N	A	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA
6500-311-000	Havasu™	08858250000303R8	I	1	N	A	
6500-315-000	Havasu™	08858250000303R8	I	1	N	A	
6500-316-000	Havasu™	08858250000303R8	I	1	N	A	

Intended Purpose

A. The Power-PRO XT™ is powered wheeled stretcher, which is intended to support and transport the entire body of a traumatized, ambulatory, or non-ambulatory human patient (includes infants and adults).

The battery-powered hydraulic lift system is intended to help reduce the effort required by the operator to raise and lower the cot. The device is designed to support patients in a supine (horizontal) or sitting position and facilitate the transportation of associated medical equipment (such as oxygen bottles, monitors, or pumps) in emergency or transport vehicles. This ambulance cot is intended to be used in pre-hospital and hospital environments, and in emergency and non-emergency applications. It is rated to a maximum capacity of 700 lb. (318 kg) (sum of the patient, mattress, and accessory weight) and the intended operators of the device are trained professionals including emergency medical service and medical care center personnel, as well as medical first responders.

Power-PRO XT is not intended for extended stay or use as a hospital bed or in devices that modify air pressure, such as hyperbaric chambers.