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-55	**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 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 [1]**	**Certificate Number [1]**
N/A	These devices conform 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	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
6390-000-000	Power-LOAD™	08858250000291RS	I	13	A	N	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A

Intended Purpose:

A. Power-LOAD is intended to assist with loading and unloading of a compatible wheeled stretcher (ambulance cot) to and from a transport vehicle and to secure the ambulance cot during transport. The device has a maximum safe working load of 870 lb (395 kg), which includes the weight of the ambulance cot, patient, and equipment attached to the cot (such as oxygen bottles, monitors, and pumps). The intended users of the device are trained professionals, including emergency medical service and medical care center personnel, as well as medical first responders, service technicians and installers.