stryker

EU Declaration of Conformity TO MEDICAL DEVICE REGULATION 2017/745			
Manufacturer (Name, Address, SRN)	Stryker Medical 3800 E. Centre Avenue 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	M0000004885	**Revision Number**	AA

Declaration

We hereby declare under our sole responsibility as the manufacturer that the products listed in Appendix A conform with the relevant provisions of the Medical Devices Regulation 2017/745 and Machinery Directive (2006/42/EC).

We hereby declare under our sole responsibility as the manufacturer that the products listed in Appendix A conform with 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 that the product indicated with an "*" in Appendix A conforms with the Radio Equipment Directive 2014/53/EU. The product is in conformity with the following standards and/or documents:

EN 60601-1:2006+A12:2014, EN 62209-2:2010, EN 62311:2020, EN 60601-1-2:2015, ETSI EN 301 489-1 V2.2.3, ETSI EN 301 489-3 V2.1.1, ETSI EN 301 489-17 V3.2.2, ETSI EN 301 489-19 V2.1.0, ETSI EN 300 330 V2.1.1, ETSI EN 300 328 V2.2.0, ETSI EN 301 893 V2.1.1, ETSI EN 303 413 V1.1.1, ETSI EG 203 367 V1.1.1

Name and Number of Notified Body [1]	**Conformity Assessment Procedure**	**Certificate Number** [1]
N/A	Devices listed in Appendix A 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

Person Responsible for Regulatory Compliance or Designee Name and Function	Melissa Lalomia, Senior Director Regulatory Affairs & Clinical Sciences
Place and Date of Issue	Portage, MI (1) Effective Date: 24-Jan-2022
Signature	Melissa Lalomia

Appendix A:

Main Devices:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule
650700000000*	Power-PRO™ 2	0885825000029 5S2	I	13

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule
650700350001	Havasu™	08858250000303R8	I	1
650700350002	Havasu™	08858250000303R8	I	1
650700350005	Havasu™	08858250000303R8	I	1
650700350006	Havasu™	08858250000303R8	I	1

Intended Purpose:

Power-PRO™ 2 is intended to transport a patient to or from an emergency or non-emergency location, primarily within an emergency transport vehicle, to a healthcare facility. Power-PRO™ 2 is not intended for extended stay or use as a hospital bed or in devices that modify air pressure, such as hyperbaric chambers.