



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-53	Revision Number	A.0

See Appendix A for Device information

We hereby declare under our sole responsibility that these products conform with the relevant provisions of the Medical Devices Regulation 2017/745.

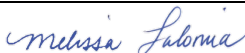
We declare, under our sole responsibility, that the products specified in the product list also conform to the following regulations and directives:
(Write N/A where applicable)

N/A

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: March 25, 2021
Signature	

Appendix A:**Main Devices:**

Product Number	Product Name	Basic UDI-DI	Risk Class	Rule	Measuring Function (Y/N)	Intended Purpose	Manufactured by
6100-003-000	M-1®	08858250000294RY	I	1	N	A	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA
6100-031-000	M-1®	08858250000294RY	I	1	N	A	

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	Rule	Measuring Function (Y/N)	Intended Purpose	Manufactured by
6100-115-000	Havasu™	08858250000303R8	I	1	N	A	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA
6100-116-000	Havasu™	08858250000303R8	I	1	N	A	
6373-000-000	M-1® Cot Fastener	08858250000293RW	I	1	N	B	
6376-000-000	M-1® Cot Fastener	08858250000293RW	I	1	N	B	
6381-000-000	M-1® Cot Fastener	08858250000293RW	I	1	N	B	

Intended Purpose

- A. The Stryker Model 6100 M-1 Roll-In System is a non-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). In emergency or transport vehicles, the product:
- Supports patients in a supine (horizontal) or sitting position
 - Facilitates the transportation of associated medical equipment (i.e. oxygen bottles or IV bags)

This ambulance cot is intended to be used in pre-hospital and hospital environments, in emergency and non-emergency applications. It is rated to a maximum capacity of 500 lb (227 kg), which is the sum of the patient, mattress, and accessory weight. Intended operators of the product include:

- Trained professionals
- Emergency medical service
- Medical care center personnel
- Medical first responders

Ambulance cots are for transportation purposes. They are not intended for extended stay or for use as hospital beds. They are also not intended for use in devices that change air pressure, such as hyperbaric chambers.

- B. The Stryker Model 6373/6376/6381 is a manual, ambulance cot fastener that secures a compatible ambulance cot during transport. The cot fastener is intended to be used in pre-hospital environments, in emergency and non-emergency applications. Operate the product by trained professionals only. This includes emergency medical service and medical first responders.