



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	M0000003021	Revision Number	AA.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	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	Portage, MI (1) Effective Date: May 12, 2021
Signature	

Appendix A:

Main Devices:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
6300-000-100	ST1 Transport Stretcher	08858250000290RQ	I	1	A	N	Muka Metal Tic. Ve San. A.S. Kayseri Serbest Bölge Şubesi 2.Cad.No:17 Melikgazi/Kayseri - TURKEY
6350-000-100	KAPADO Transport Stretcher	08858250000290RQ	I	1	A	N	
6300-000-200	ST1-X Transport Stretcher	08858250000289S7	I	1	A	N	
6350-000-200	KAPADO-X Transport Stretcher	08858250000289S7	I	1	A	N	

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
MM050	Removable IV Pole	08858250000303R8	I	1	A	N	Muka Metal Tic. Ve San. A.S. Kayseri Serbest Bölge Şubesi 2.Cad.No:17 Melikgazi/Kayseri - TURKEY
MM052	Ankle Restraint Strap	08858250000300R2	I	1	A	N	
MM054	Wrist Restraint Strap	08858250000300R2	I	1	A	N	
MM056	Body Restraint Straps	08858250000300R2	I	1	A	N	
MM057	Body Restraint Straps	08858250000300R2	I	1	A	N	

Intended Use

A.

The Stryker Model 6300, ST1 & ST1-X stretcher and Model 6350, KAPADO & KAPADO-X are wheeled devices which consist of a platform mounted on a wheeled frame to support patients in a horizontal position. The stretcher is for use by human patients in a MedSurg setting, as a short-term outpatient clinical evaluation, treatment, minor procedure, and short-term outpatient recovery platform.