



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	M0000003022	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 hereby declare under our sole responsibility that these products conform to the harmonized standard EN50581, and thereby comply with the European Directive 2011/65/EU (RoHS2) as amended including commission delegated Directive 2015/863 (RoHS3).			
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	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
7500-000-000	SV2 Electric Hospital Bed	08858251002008S2	I	13	A	N	Muka Metal Tic. Ve San. A.S. Kayseri Serbest Bölge Şubesi 2.Cad.No:17 Melikgazi/Kayseri - TURKEY
7500-000-050	SV2 Electric Hospital Bed	08858251002008S2	I	13	A	N	
7500-000-200	SV2 Electric Hospital Bed	08858251002008S2	I	13	A	N	
7500-000-300	SV2 Electric Hospital Bed	08858251002009S4	I	13	A	N	
7600-000-050	Argaios 250 Electric Hospital Bed	08858251002008S2	I	13	A	N	
7600-000-100	Argaios 250 Plus Electric Hospital Bed	08858251002008S2	I	13	A	N	
7600-000-300	Argaios 300 Electric Hospital Bed	08858251002008S2	I	13	A	N	

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
7002-2-012	Foam Mattress	08858250000284RV	I	1	B	N	Muka Metal Tic. Ve San. A.S. Kayseri Serbest Bölge Şubesi 2.Cad.No:17 Melikgazi/Kayseri - TURKEY
7002-2-014	Foam Mattress	08858250000284RV	I	1	B	N	
7002-5-012	Foam Mattress	08858250000284RV	I	1	B	N	
7002-4-018	Foam Mattress	08858250000284RV	I	1	B	N	
7002-4-020	Foam Mattress	08858250000284RV	I	1	B	N	
7002-2-512	Foam Mattress	08858250000284RV	I	1	B	N	
7002-5-512	Foam Mattress	08858250000284RV	I	1	B	N	
7002-2-514	Foam Mattress	08858250000284RV	I	1	B	N	
7002-4-518	Foam Mattress	08858250000284RV	I	1	B	N	
7002-4-520	Foam Mattress	08858250000284RV	I	1	B	N	
7002-5-712	Foam Mattress	08858250000284RV	I	1	B	N	
MM029	Foley Bag Basket	08858251002007RY	I	1	A	N	
MM017	IV Pole	08858250000303R8	I	1	A	N	
MM060	IV Pole	08858250000303R8	I	1	A	N	

Intended Use

A.

SV2 & ARGAIOS are electromechanical MedSurg and ICU beds with DC-powered actuators and controls to adjust the patient sleep surface. The patient sleeping surface consists of four sections: the backrest, seat, upper leg section, and lower leg sections. Siderails are split, with two siderails on the head end, and two siderails on the foot end. The siderails secure in the full up position. When unlatched, siderails open outside and move to the lowest position.

SV2 & ARGAIOS are for use by human adult patients in a MedSurg and ICU setting requiring the support of a hospital bed. SV2 & ARGAIOS are for use in medical, surgical, and critical care healthcare environments, including hospitals, institutions and clinics. The SV2 & ARGAIOS bed frame, litter mounted accessories, and mattresses can come in contact with human skin.

B.

The 7002 mattresses are for use as a rest or sleep surface for human adult patients in a hospital setting. The SV series mattresses are intended to assist in the prevention and treatment of Pressure Ulcer Stages (I, II, III, IV, Unstageable and Deep Tissue Ulcers or all pressure ulcers) and are recommended to be implemented in combination with clinical evaluation of risk factors and skin assessments made by a health care professional.