



EU Declaration of Conformity  
TO MEDICAL DEVICE REGULATION 2017/745

<b>Manufacturer (Name, Address, SRN)</b>	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA SRN: US-MF-000000542		
<b>EU Authorized Representative Name, Address</b>	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co Cork, T45 HX08 Ireland		
<b>Declaration of Conformity Document Number</b>	DOC-73	<b>Revision Number</b>	A.1
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). Products indicated with “*” on the product list are exempt from the scope of the RoHS 2 Directive 2011/65/EU.			
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)	
<b>Name and Number of Notified Body <sup>[1]</sup></b>	<b>Conformity Assessment Procedure <sup>[1]</sup></b>	<b>Certificate Number <sup>[1]</sup></b>	
N/A	These devices conform to the requirements of Annex II and Annex III of Regulation (EU) 2017/745.	N/A	
<sup>[1]</sup> This section is N/A for Class I (self-certified) devices.			
<b>Reference to Common Specifications</b> (Write N/A when not applicable)	N/A		
<b>Additional Information</b> (Write N/A when not applicable)	N/A		
<b>Person Responsible for Regulatory Compliance or Designee Name and Function</b>		Melissa Lalomia, Senior Director Regulatory Affairs & Clinical Sciences	
<b>Place and Date of Issue</b>		Portage, MI (1) Effective Date: February 12, 2021	
<b>Signature</b>			

**Appendix A:****Main Devices:**

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose	Measuring Function (Y/N)	Manufactured by
*1125-000-026	Prime Series® Zoom®	08858250000290RQ	I	1	A	N	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA
*1125-000-030	Prime Series® Zoom®	08858250000290RQ	I	1	A	N	
*1125-000-000X	Prime Series® Zoom®	08858250000289S7	I	1	A	N	
1125-000-000E	Prime Series® Zoom®	08858250000288S5	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
0785-045-016	Restraint Strap	08858250000300R2	I	1	A	N	JAC Manufacturing, Inc. 56525 Woodhouse Drive Dowagiac, MI 49047 USA
0785-045-017	Restraint Strap	08858250000300R2	I	1	A	N	
0785-045-020	Restraint Strap	08858250000300R2	I	1	A	N	
0390-019-001	Restraint Strap	08858250000300R2	I	1	A	N	
0390-019-002	Restraint Strap	08858250000300R2	I	1	A	N	
0946-044-001	Restraint Strap	08858250000300R2	I	1	A	N	
0390-025-000	Havasut <sup>TM</sup>	08858250000303R8	I	1	A	N	J. Sterling Industries, LTD 87 Sharer Road Woodbridge, ON L4L 8Z3 CAN
0785-035-101	Havasut <sup>TM</sup>	08858250000303R8	I	1	A	N	
0785-035-200	Havasut <sup>TM</sup>	08858250000303R8	I	1	A	N	
0785-035-300	Havasut <sup>TM</sup>	08858250000303R8	I	1	A	N	
0785-035-401	Havasut <sup>TM</sup>	08858250000303R8	I	1	A	N	
*1105-045-100	X-Ray Cassette Holder	08858250000302R6	I	1	A	N	Stryker Medical 3800 E. Centre Ave. Portage, MI 49002 USA
*1105-045-300	X-Ray Cassette Holder	08858250000302R6	I	1	A	N	

Intended Purpose:

- A. The Stryker Model 1125 Prime Series stretcher with Zoom Motorized Drive is an electromechanical stretcher that provides a healthcare professional or trained representative greater maneuverability in steering and moving the stretcher with significantly less force.

The Prime Series stretcher may be used as a short-term outpatient clinical evaluation, treatment, minor procedure, and short-term outpatient recovery platform. The stretcher may include use in, but is not limited to:

- Emergency Department (ED)
- Trauma area
- Post-Anesthesia Care Unit (PACU)

The Prime Series stretcher may be used for minor procedures and short-term stay (treatment and recovery). See the specifications table for the intended environmental conditions.

The Stryker Prime Series Stretcher has not been evaluated for compliance to bed standard BS EN 50637. This product is not intended for use for short term stay with pediatric patients or adult patients with atypical anatomy in markets that recognize this bed standard for market authorization.

The Prime Series stretcher has a safe working load up to 700 lb (318 kg) and is intended to be used with all patients, including those mildly to critically ill. The stretcher may also be used to transport deceased patients within an enclosed healthcare facility.

The Prime X<sup>®</sup> option provides an articulating radiographic patient support surface and a platform below the patient support surface for X-ray cassette placement. The Prime X option is intended to allow the capture of clinical X-rays (AP full body, optional full body lateral, and optional upright chest) when used with a medical X-ray system.