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		
EU Authorized Representative – Packaging (Name and Address)	N/A – Authorized Representative for packaging has not yet been identified by Stryker Corporation.		
Declaration of Conformity Document Number	DOC-73	**Revision Number**	E

Declaration

We hereby declare under our sole responsibility as the manufacturer that the product(s) 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 product(s) identified with a "*" 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 as the manufacturer that the product(s) identified with a "†" in Appendix A conform with the Radio Equipment Directive 2014/53/EU. The product is in conformity with the following standards and/or documents:

EN 60601-1:2006+A13:2024, EN 60601-1-2: 2015+A1:2021, EN 62311:2020, ETSI EN 300 328 V2.2.2, ETSI EN 301 489-1, Ed. 2.2.3, ETSI EN 301 489-17, V3.2.4, ETSI EN 301 893, V2.1.1

We hereby declare under our sole responsibility as the manufacturer that the product(s) identified in Appendix A conform with the relevant provisions of (EU) 2025/40 – Packaging and Packaging Waste Regulation (PPWR).

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 the Medical Devices Regulation 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

Appendix A:

Main Devices:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose
*1125-000-026	Prime Series® Zoom®	08858250000286RZ	I	13	A
*1125-000-030	Prime Series® Zoom®	08858250000286RZ	I	13	A
*1125-000-000X	Prime Series® Zoom®	08858250000285RX	I	13	A
*†1125-000-000E	Prime Series® Zoom®	08858251002085SL	I	13	A
*†1125-000-000C	Prime Series® Zoom®	08858251002085SL	I	13	A

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule	Intended Purpose
0390-019-001	Restraint Strap	08858250000300R2	I	1	A
0390-019-002	Restraint Strap	08858250000300R2	I	1	A
0785-045-020	Restraint Strap	08858250000300R2	I	1	A
0785-045-016	Restraint Strap	08858250000300R2	I	1	A
0785-045-017	Restraint Strap	08858250000300R2	I	1	A
0946-044-001	Restraint Strap	08858250000300R2	I	1	A
0946-043-001	Restraint Strap	08858250000300R2	I	1	A
0785-035-101	Havasu®	08858250000303R8	I	1	A
0785-035-401	Havasu®	08858250000303R8	I	1	A
0785-035-200	Havasu®	08858250000303R8	I	1	A
0785-035-300	Havasu®	08858250000303R8	I	1	A
0390-025-000	Havasu®	08858250000303R8	I	1	A
1105-045-100	X-Ray Cassette Holder	08858250000302R6	I	1	A
1105-045-300	X-Ray Cassette Holder	08858250000302R6	I	1	A

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).

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® 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.

Packaging:

Detailed reference numbers and supporting compliance evidence are contained in M00000032458, Stryker Medical Kalamazoo Packaging and Packaging Waste Regulation (PPWR) Technical Report.

PRRC or Designee Name and Function	Divya Murali Director, Global Regulatory Affairs
Place and Date of Issue	Portage, MI Effective Date: August 12, 2026
Signature