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 and Address)	Stryker European Operations Limited Anngrove, IDA Business & Technology Park Carrigtwohill, Co. Cork, T45 HX08 Ireland		
Declaration of Conformity Document Number	DOC-82	**Revision Number**	D

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) listed 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) indicated with an "*" in Appendix A conform with the Radio Equipment Directive 2014/53/EU. The products are in conformity with the following standards:

EN 60601-1:2006+A12:2014, EN 62209-2:2010, EN 60601-1-2:2015, ETSI EN 301 489-1 V2.2.3, ETSI EN 301 489-17 V3.2.4, ETSI EN 300 328 V2.2.2, ETSI EN 301 893 V2.1.1, EN 62479:2010

We hereby declare under our sole responsibility as the manufacturer that the product(s) identified with an "+" in Appendix A conform with the harmonized standard BS EN 45501:2015 and Directive 2014/31/EU (NAWI). The notified body Force Certification A/S (0200) performed conformity assessment procedure Module B and issued the certificate 0200-NAWI-08329. The notified body NMI Certin B.V. (0122) performed conformity assessment procedure Module D and issued the certificate CE-379.

Name and Number of Notified Body [1]	**Conformity Assessment Procedure**	**Certificate Number** [1]
BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands Phone : +31 (0)20 346 07 80 Notified Body number: 2797	Conformity assessment based on an examination of the quality system and technical documentation in accordance with Regulation (EU) 2017/745 Annex IX Chapter I and III.	MDR 731073

[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 Device:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule
*+300900000000	ProCuity™	08858251002172SG	Im	13

Accessories:

Product Number	Product Name	Basic UDI-DI	Risk Class	MDR Classification Rule
300900350100	Havasu™	08858250000303R8	I	1
300900350200	Havasu™			
300900350250	Havasu™			
300900670805	ProCuity™ Foam-filled bed mattress	08858250000282RR	I	1
300900670905	ProCuity™ Foam-filled bed mattress	08858250000282RR	I	1
*521200380100[1]	Secure® Connect™	08858251002473SZ	I	13

[1] Secure® Connect™ conforms to Directive 2014/53/EU (RED) and standards listed excluding EN 62209-2:2010 and ETSI EN 301 893 V2.1.1 as these are not applicable.

Intended Purpose:

The ProCuity bed series is intended for use to assist with positioning, therapy, recovery, support, and transport of patients within a healthcare delivery organization (HDO). The intended user is both HCPs (nurses, nurse aides, and medical doctors) and human patients.

This product can be used with human patients that weigh more than 60 lb (27.2 kg), with a maximum height of 84 inches (213.4 cm) without the bed extender or 96 inches (243.84 cm) with the bed extender.

The scale output is not intended to be used to determine diagnosis or treatment.

The ProCuity bed series has not been evaluated for compliance to bed standard BS EN 50637. This product is not intended for use with pediatric patients or adult patients with atypical anatomy in markets that recognize this bed standard for market authorization.

This product is not intended for:
- Behavioral health patient use
- Oxygen rich environments
- Sterile environments
- Home care or non-institutional long-term care facility settings

PRRC or Designee Name and Function	Divya Murali, Director Global Regulatory Affairs
Place and Date of Issue	Portage, MI Effective Date: 17-Feb-2025
Signature