



EU Declaration of Conformity  
TO MEDICAL DEVICE REGULATION 2017/745

|  |  |  |     |
|--|--|--|-----|
| <b>Manufacturer (Name, Address, SRN)</b>   | Stryker Medical<br>3800 E. Centre Ave.<br>Portage, MI 49002 USA<br>SRN: US-MF-000000542  |  |     |
| <b>EU Authorized Representative Name, Address</b>  | Stryker European Operations Limited<br>Anngrove, IDA Business & Technology Park<br>Carrigtwohill, Co Cork, T45 HX08<br>Ireland |  |     |
| <b>Declaration of Conformity Document Number</b>   | DOC-66   | <b>Revision Number</b>                   | A.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:<br>(Write N/A where applicable) | N/A  |  |     |
|  |  |  |     |
|  |  |  |     |
| <b>Name and Number of Notified Body <sup>[1]</sup></b>   | <b>Conformity Assessment Procedure</b>   | <b>Certificate Number <sup>[1]</sup></b> |     |
| N/A  | This device conforms 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><br>(Write N/A when not applicable)   | N/A  |  |     |
| <b>Additional Information</b><br>(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 <sup>(1)</sup></b>  | Portage, MI<br>(1) Effective Date: March 12, 2021  |  |     |
| <b>Signature</b>   |  |  |     |

Appendix A:

Main Devices:

| Product Number | Product Name | Basic UDI-DI     | Risk Class | Rule | Measuring Function (Y/N) | Intended Purpose | Manufactured by  |
|----------------|--------------|------------------|------------|------|--------------------------|------------------|--|
| 1460-000-000   | Prime TC®    | 08858250000278S2 | I          | 1    | N                        | A                | Stryker Medical<br>3800 E. Centre Ave.<br>Portage, MI 49002<br>USA |

#### Accessories:

| Product Number | Product Name | Basic UDI-DI     | Risk Class | Rule | Measuring Function (Y/N) | Intended Purpose | Manufactured by  |
|----------------|--------------|------------------|------------|------|--------------------------|------------------|--|
| 1460-035-021   | Havasu™      | 08858250000303R8 | I          | 1    | N                        | A                | Stryker Medical<br>3800 E. Centre Ave.<br>Portage, MI 49002<br>USA |

#### Intended Purpose

- A. Prime TC is a transport chair that is intended for medical purposes to assist a person in performing an activity that the person would find difficult to do or be unable to do. Prime TC is intended for occupants who have the ability to hold themselves in an upright, seated position, unassisted, and in compliance with facility guidelines for transporting.

Expected use of Prime TC is to support the occupant in an upright, seated position with their back against the seat back and their feet and arms on the provided resting surfaces. For transport, the operator pushes the chair from behind by gripping the provided handles. Users should not sit on the arms, stand upright on any surface, or lean on the arms or seat back from a standing position. Intended operators include healthcare transporters (escorts), nurses, other healthcare professionals, family members, and individuals who accompany the occupant.

Prime TC is intended for use inside healthcare facilities and outside healthcare facilities, and in adjacent locations, including parking lots. Transport activity includes curbside admissions and discharge, interdepartmental and intradepartmental transport, and transport in elevators. Prime TC has a safe working load of 500 lb. (226.8 kg), including occupant and accessories. The typical duration of use can vary from several minutes to up to an hour. However, occupant wait time for certain events (for example, awaiting CT scan, MRI scan, or an X-ray) may exceed an hour.