



## EU-declaration of conformity

As manufacturer  
**Panthera AB**  
Gunnebogatan 26  
SE-163 53 Spånga  
Sweden



declares under the sole responsibility that below specified product is in conformity with the

**Regulation (EU) 2017/745**  
on medical devices (MDR)

**General description** Manual wheelchair.

Intended use:

*Panthera wheelchair model U3 Light and X is intended for individuals who need an active manual wheelchair for everyday use both in- and outdoors. These wheelchairs are indicated for persons with physical disabilities and use isn't restricted to a specific diagnosis. It is the individual capacity of functioning that indicates the need of a manual active wheelchair as technical aid for transferring. Recommendations for a wheelchair should be given by educated healthcare providers and thereafter a suitable product is trialed and configured for optimized seating- and driving properties by an expert. The set-up and configuration of the wheelchair is chosen for each individual and the products are in most cases not suitable for small children.*

The trade name of the wheelchair is **Panthera U3 Light / X** and is manufactured by Panthera AB. The manufacturer's internal article number(s) is/are **U3 Light: G557, G5805, G5806, G5808, G5809; X: G350,**

**Basic UDI-DI**

**U3 Light: 73400001U3LPE; X: 73400001XN8**

**SRN**

**SE-MF-000014594**

**Product class:**

Class I (according to Annex VIII Chapter III, rule 1)

**Standards**

Conformity to the general safety and performance requirements have been demonstrated by using the following standards:

EN ISO 9001:2015

EN ISO 14971:2019

EN 12183:2014

EN ISO 7176-8:2014

EN ISO 7176-16:2012

EN ISO 15223-1:2021

EN ISO 20417:2021

EN ISO 10993-1:2009

EN ISO 10993-5:2009

EN ISO 10993-18:2005

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Spånga, Sweden

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On behalf of Panthera AB

[Fredrik Skantz] / Site Manager