



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; 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

Original drawn up 2021-12-29

Place and date: Spånga, Sweden
2021-12-29

On behalf of Panthera AB

[Fredrik Skantz] / CEO