



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 purpose:

Panthera wheelchair model Bambino 3 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.

The trade name of the wheelchair is **Panthera Bambino 3** and is manufactured by Panthera AB. The manufacturer's internal article number(s) is/are: G517, G518

Basic UDI-DI

73400001B33F

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 15223-1:2021
EN ISO 20417:2021
EN ISO 7176-16:2012
EN ISO 7176-8:2014
EN ISO 7176-19:2008
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