

panthera

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 Micro 3 is intended for small children (up to approximately 5 years of age) who need an active manual wheelchair for everyday use. This wheelchair is indicated for persons with physical disabilities and use is not 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 trade name of the wheelchair is **Micro 3** and is manufactured by Panthera AB. The manufacturer's internal article number(s) is: G515

Basic UDI-DI 73400001M34G

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 7176-8:2014
EN ISO 7176-16:2012
EN ISO 20417:2021
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-18:2005

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On behalf of Panthera AB

[Fredrik Skantz] / CEO