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 S3 Swing wheelchairs are built for individuals who need a manual dynamic wheelchair for everyday use, both inside and outside the home. These wheelchairs are made to be used by people with physical disabilities, and are not limited to people with a specific diagnosis. Each person's individual function capacity and limitations indicates whether a manual dynamic wheelchair is suitable as a mobility aid. Wheelchair model recommendations should be given by trained healthcare professionals, and the appropriate product should then be tested and adjusted by an expert for the optimal sitting and driving characteristics The wheelchair's design and settings are tested for each individual, and the product is not usually suitable for young children.

The trade name of the wheelchair is Panthera S3 Swing

and is manufactured by Panthera AB. The manufacturer's internal article number(s)

are: G547, G553, G581, G5818, G5837

Basic UDI-DI

73400001S3SWINGAZ

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 1021-1:2006 EN ISO 7176-8:2014 EN ISO 7176-19:2008 EN ISO 10993-1:2009 EN ISO 10993-5:2009

EN ISO 10993-5:2009 EN ISO 10993-18:2005

Original drawn up

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Place and date:

Spånga, Sweden

2021-12-29

On behalf of Panthera AB

[Fredrik Skantz] / CEO