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 models S3 and U3 are 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 S3/U3**
and is manufactured by Panthera AB. The manufacturer's internal article number(s) is/are
S3: G548, G549, G552, G555, G583, G554, G5831
U3: G551,G584, G5801, G5802

Basic UDI-DI	**73400001S352**
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
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On behalf of Panthera AB

[Fredrik Skantz]
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