

EU Declaration of Conformity

Manufacturer

Name: Svan Care AB

Adress: Alvägen 1, 771 41 Ludvika, Sverige

SRN: -

Svan Care AB declares under sole responsibility that the product **Balance, with article number 10101-10110 and Basic UDI-DI 7350011590162TD** conforms to applicable requirements and general safety and performance requirements of EU regulation on medical devices (MDR 2017/745, Annex I, II, III and IV), which are applicable for the product and product class I, to which this belongs according to MDR 2017/745, Annex VIII.

Balance is a device that helps the whole family of users with difficulties with balancing in standing and sitting position during use of the toilet. With help from the included armrests and footrest the user can get stabilization, the device is also foldable to enable members of the whole family not needing support to easily use the toilet.

The product is CE-marked and complete documentation according to Annex II for MDR 2017/745, is available. The product complies to the following standards:

EN 12182:2012 Assistive products for persons with disability - General requirements and test methods.

Ludvika 2020-05-25



Jan Nordin, CEO

