EU Declaration of Conformity

Manufacturer

Njord International AB
Medicinaregatan 8
413 90 Göteborg
Sweden
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SRN: SE-MF-000024137

Product

Product Name	REF No.	Basic UDI-DI	From S/N
ATLE® 180	20,000	735014575Atle1805A	00064

Components and spare parts, see Annex 1.

Intended purpose

Alte® 180 is a motorized lateral patient transfer aid that is intended to be used in clinical or care environments to transfer patients between horizontal patient platforms, e.g. between a bed and an examination table. The device is intended to be used by healthcare professionals for patients with a maximum weight of 180 kg.

Classification (according to (EU) 2017/745, Annex VIII): Class I (Rule 13)

Declaration of Conformity

We, Njord International AB, hereby declare under our sole responsibility, that the product to which this declaration relates fulfils the requirements of the Regulation (EU) 2017/745 (MDR) and the directives 2014/30/EU (RED), 2014/35/EU (LVD) and 2011/65/EU (RoHS).

Significant changes to the medical device provoke a loss of validity.

Place and Date

Göteborg, Sweden, 2025-02-20

Jacob Ahrnstein
CEO
Njord International AB

Annex 1

Component Name	REF No.
Transfer Bar	20,001
Hand Control	20,002
Line with bobbin	20,167
Charger	20,004