

The undersigned, representing the following manufacturer

Decon Wheel AB
Org.No. 556618-9006
Södra Ekeryd 119, 314 91 Hyltebruk
Sweden

hereby declares that the product

E-Drive

with the basic UDI-DI 735001014MEDB3

and the following references

MED316		MEDL316	
MED320	MED320HD	MEDL320	MEDL320HD
MED322	MED322HD	MEDL322	MEDL322HD
MED324	MED324HD	MEDL324	MEDL324HD
MED325	MED325HD	MEDL325	MEDL325HD
MED326	MED326HD	MEDL326	MEDL326HD

is in conformity with the Medical Device Regulation (MDR) 2017/745 as a class I medical device based on Annex VIII; and the Directive (RoHS) 2011/65/EU.

Intended purpose: The device is an electric drive unit for manual wheelchairs with the intention to provide mobility and flexibility to persons who are unable to walk or have restrictions on walking. The device is intended for indoor and outdoor use.

This EU declaration of conformity is issued according to Annex IV in MDR and under sole responsibility of the manufacturer.

Hyltebruk, 2023-05-22



Benny Andersson
COO

