



The undersigned, representing the following manufacturer

Decon Wheel AB
Org. No. 556618-9006
SRN SE-MF-000046289
Södra Ekeryd 119, 314 91 Hyltebruk
Sweden,

hereby declares that the product **E-Drive NXT**

with the basic UDI-DI 735001014MEDB3

and the following references

MEDL416		
MEDL420	MEDL420HD	
MEDL422	MEDL422HD	
MEDL424	MEDL424HD	MEDL424M
MEDL425	MEDL425HD	
MEDL426	MEDL426HD	MEDL426M

is in conformity with the Medical Device Regulation (EU) 2017/745 as a class I medical device based on Annex VIII, in accordance with Annex II and Annex III; and the Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

The product incorporates a rechargeable Li-ion battery which is CE-marked and covered by a separate EU Declaration of Conformity issued under Regulation (EU) 2023/1542 on batteries and waste batteries.

Intended purpose: E-Drive NXT is an electrically powered drive unit intended to be mounted onto compatible manual wheelchairs to provide powered assistance and braking support during propulsion of individuals who are unable to walk or who have limited walking ability.

This EU declaration of conformity is issued under the sole responsibility of the manufacturer.

Hyltebruk, 2026-04-17

Mattias Lundin
CEO

